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PAIN AND FUNCTIONAL OUTCOMES AFTER TOTAL HIP AND KNEE ARTHROPLASTIES. A PROSPECTIVE STUDY OF A COMMUNITY-BASED COHORT.

by

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled PAIN AND FUNCTIONAL OUTCOMES AFTER TOTAL HIP AND KNEE ARTHROPLASTIES. A PROSPECTIVE STUDY OF A COMMUNITY-BASED COHORT submitted by Catherine Allyson Jones in partial fulfillment of the requirements for the degree of DOCTOR OF PHILOSOPHY in Medical Science-Public Health Sciences.

DEDICATION

This thesis is dedicated to the influential women in my life, my mother, Marguerite Lorraine Jones (nee Smith), my grandmother, Marguerite Evagaline Smith (nee McKay), and my great-grandmother, Lena McKay (nee Gooselin) who set exemplifying roles. They showed me that all goals are possible given a belief in one self, a concern for others and perseverance.

ABSTRACT

Pain and functional outcomes after total hip and knee arthroplasties (THA / TKA) were examined in a community-based cohort. The primary objectives of this study were: 1) to quantify the magnitude of change seen in pain, function, and overall health status outcomes after THA and TKA, 2) to determine the effect of age on these outcomes, and 3) to identify determinants of pain and function.

A consecutive cohort of 504 patients who were placed on the waiting list from December 18, 1995 to January 24, 1997 for elective THA (228) or TKA (276) was assembled within a Canadian health region (Edmonton, AB). All patients resided in the community and in-person interviews were conducted within 1 month prior to surgery and 6 months afterward.

The interview consisted of a disease-specific questionnaire, *Western Ontario and McMaster Universities* (WOMAC) *Osteoarthritis Index*, a generic health status questionnaire, *SF-36 Health Survey* (SF-36), and questions regarding comorbidities and socio-demographic characteristics. Peri-operative factors were extracted from medical charts. Health services utilization data were collected from regional health databases.

While large improvements were reported in pain and function, moderate to small changes were also seen with other health-related quality of life factors. Change was greater for pain than function while greater gains were reported with THA than TKA.

No differences in pain, function or overall health status were seen between patients who were 80 years or older and patients 55 to 79 years of age. Furthermore, after controlling for potential confounding effects of such variables as comorbid conditions and pre-operative function, age was not a significant factor. These findings suggests that age alone is not a factor affecting the outcome of surgery

Demographic and clinical variables explored through multiple linear and logistic regressions did not identify any one single factor that could predict either pain or function. Patients who reported less pain relief or functional improvements tended to have more comorbid conditions and less pre-operative pain. While this study described the outcomes and examined possible determinants of pain and function after THA and TKA, further studies are needed to assess other possible determinants over a longer period of time.

PREFACE

The doctoral research presented examines pain, function and overall health in an inception community-based cohort of patients who were receiving either total hip or knee arthroplasty. The three objectives of this research were: a) to quantify the amount of change seen in pain, function and health-related quality of life, b) to determine the effect of age on pain, function and health-related quality of life after surgery, and c) to identify determinants of pain and functional improvement.

These objectives were developed by the author in response to the rehabilitation and health services utilization concerns that many healthcare professionals express when treating this patient population. A further impetus in developing this research is the well-recognized methodologically weak study designs reported in the literature regarding joint arthroplasties. [1,2]

Patients were initially assembled from another study that examined waiting list times; however, sufficient funds were available to follow these patients after their surgeries to achieve this study's objectives. Because patients were identified at the time when surgery was deemed necessary, this provided a unique opportunity to examine an inception cohort of patients requiring joint arthroplasties. To date, no study has prospectively evaluated this type of cohort within a joint arthroplasty patient population.

Funding was originally secured through the Capital Health Authority Research Development Fund to examine waiting list times for patients receiving total hip and knee arthroplasties within the Capital Health Region (Edmonton and surrounding areas). In response to a growing demand for joint replacements and scarcity of surgical resources, waiting times for joint replacements were perceived to be growing by the healthcare and public sectors. A preliminary assessment of the waiting times over a three month period within the health region was subsequently completed by Drs. Redfern and Voaklander (1995).[3] From these preliminary findings, a grant was developed to address issues surrounding equitable access to surgery based on the burden of symptoms expressed by patients waiting for joint arthroplasties. The specific aims of the waiting list study were to identify those factors related to waiting times and to quantify the burden of symptoms of persons waiting for total hip and knee arthroplasties.

To ensure follow-up of these patients after their surgeries and achieve the objectives of this present research, the author participated with the principal investigators in all phases of the research such as study design/methodology/implementation and measurement selection. Patients were recruited from December 1995 to

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[1] Gartland JJ: Orthopaedic clinical research. Deficiencies in experimental design and determinations of outcomes. *JBJS* 1988; 70-A:9:1357-1371

[2] Callahan CM, Drake BG, Heck DA, Dittus RS: Patient outcomes following tricompartmental total knee replacement. A meta-analysis. *JAMA* 1994; 271:17:1349-1357

[3] Redfern L, Voaklander DC: Unpublished data on joint replacement waiting lists in the Capital Health Authority. 1995

January 1997 and they went on to have their surgeries from January 1996 to February 1998. Data were gathered by the author from a variety of sources; patient questionnaires, chart reviews, and administrative databases, to ensure the comprehensiveness and accuracy of the data.

The author took primary responsibility for the development of the research objectives, chart reviews, database management, data analyses, as well as oral and written presentations of these findings. The author's background in physical therapy provided a relevant perspective to the development and design of this research project. Since the completion of this phase, the author along with one of the original principal investigators has secured funding for a three year follow-up of this patient group. In collaboration with the principal investigator, the author developed the methodology and analyses for this follow-up study. Information to be gained from this prospective follow-up will prove valuable in determining the long-term pain and functional outcomes in light of the longevity of the prostheses.

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I would like to express my sincere gratitude to my advisor, Dr. Maria Suarez-Almazor for sharing of her extensive knowledge and support throughout my studies. Her mentorship was invaluable in completing this course of studies and thesis. Special appreciation is also expressed towards my committee members, Dr. Don Voaklander for his direction and liaison with agencies throughout the course of this research project, Dr. Duncan Saunders for his contemplative analyses, and Dr. Michele Crites Battié for her clinical perspective and encouragement.

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Lastly, I would like to thank my family for their never-ending support and love during my studies. Particularly, to my father for his philosophical outlook on life, to my mother for her astute insightfulness, to my younger brother, David for his humour and invaluable technical support, and to my other siblings, Kevin and Leah for their encouragement. Special gratitude is also expressed towards Ernie for his patience and acceptance over the past year.

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CHAPTER 1

INTRODUCTION

1.0 Overview

The thesis introduction presents an overview of the issues surrounding pain and function outcomes of joint arthroplasties. The specific aims of the research are subsequently discussed. This is followed by a literature review and the series of papers which examine joint arthroplasties in relation to a) pain, function, and health-related quality of life, b) age, and c) possible determinants of pain and function. Each of the three papers is complete within itself, yet contributes to the overall evaluation of joint arthroplasties presented in this thesis. The final section draws the links between the papers and provides a rationale for this research. The results from all three papers are discussed within the framework of this thesis and in relation to existing literature.

1.1 Statement of the Problem

Advanced stages of arthritis are not only painful and physically limiting, but overall quality of life is affected [Laupacis et al, 1993; Bellamy et al, 1989; Sherrer et al, 1986]. When conservative management fails to alleviate pain, total hip and knee arthroplasties (THA / TKA) are effective surgical means to relieve pain and improve function [Laupacis et al, 1993; Bayley et al, 1995; Callahan et al, 1994]. Over the two past decades, utilization rates for joint replacements have markedly increased and thus appear to be a corollary of an aging population and technological advancements. As utilization rates continue to increase for this elective surgery, it is unclear what factors affect the outcome and allow a patient to function independently.

It is not surprising that utilization rates for joint arthroplasties have been increasing because prevalence studies report that arthritis is the most common orthopaedic condition in the elderly population [Cunningham & Kelsey, 1984]. In particular, osteoarthritis of the hip and knee can cause pain and dysfunction. Data from the *U.S. Health and Nutrition Examination Survey* (HANES I) indicate that over half of the population 60 years or older experience moderate to severe pain of either the hip or knee. This pain may be sufficient to limit functional activities such as walking and stair climbing. Although pain and functional loss are the primary clinical features of arthritis, psychological and social dimensions may also be affected [Weinberger et al, 1990; Bradley, 1985; Meenan et al, 1980].

When conservative management of joint pain and dysfunction is insufficient, THA and TKA are surgical options. Joint arthroplasties are typically elective surgeries performed on patients between 60 and 75 years of age [Quam et al, 1991; Madhok et al, 1993; NIH, 1995; Callahan et al, 1994]. More than 123,000 THA and 120,000 TKA are performed annually in the U.S. [NIH, 1994; Callahan, et al 1994]. Because of favourable outcomes, an aging population and technological advancements, utilization rates

have steadily increased [Quam et al, 1991; Madhok et al, 1993, Overgaard et al, 1992]. In spite of the clinical popularity, few studies have prospectively evaluated the patient-related outcomes after THA or TKA [Aaron et al, 1996; Rissanen et al, 1996; Anderson et al, 1996; Sharma et al, 1996; McGuigan et al, 1995; Laupacis et al, 1993]. Moreover, no studies have prospectively followed a community-based cohort using patient-related outcomes in this patient population.

Pain and functional capacity are primary considerations for joint arthroplasties, yet earlier studies evaluated THA and TKA in terms of technical ratings, clinical impairment, health services utilization, post-operative complications, mortality, and revisions [Callahan et al, 1994; Drake et al, 1994; Gartland, 1988; Lavernia & Guzman 1995; Baron et al, 1996; Whittle et al, 1993; Homlberg, 1992; Seagroatt et al, 1991]. These outcomes are not directly reflective of pain or function; however, more recent studies have used patient questionnaires to evaluate pain, function, and health-related quality of life (HRQoL) [Hawker et al, 1998; Laupacis et al, 1993, Bayley et al, 1995; Rissanen et al, 1996; Ritter et al 1995].

The use of both disease-specific and generic health measures are recommended to evaluate pain, function and quality of life after joint arthroplasties [Kantz et al, 1992; Bombardier et al, 1995; Patrick & Deyo, 1989]. Findings using these types of measures concur that the greatest improvement occurs within the first 3 to 6 months after surgery [Laupacis et al, 1993; MacWilliam et al, 1996; Rissanen et al, 1997, Aarons et al, 1996]. Greater gains are seen with pain than function [MacWilliam et al, 1996, Laupacis et al, 1993; Rissanen et al, 1996; Rissanen et al, 1995]. In excess of 75% of patients who underwent either THA or TKA reported pain relief and functional improvement; however, the magnitude of improvement has not been clearly distinguished [Callahan et al, 1994]. Furthermore, a higher percentage of patients with THA reported improvement than patients with TKA [Ritter et al, 1995; Rissanen et al, 1995; Kirwan et al, 1994].

Although joint arthroplasties provide pain relief and improve function, clinical evidence show that both THA and TKA affect other general well-being dimensions such as social function, mental health and vitality after surgery [Laupacis et al, 1993; Bayley et al, 1995; Ritter et al, 1995; McGuigan et al, 1995; Rissanen et al, 1995; Aarons et al, 1996]. Improvements are reported up to two years after surgery, yet the gains seen with HRQoL are less than the improvements reported with pain and function [Rissanen et al, 1995; Ritter et al 1995; Bayley et al, 1995]. Findings from previous studies are unclear as to whether the gains seen with HRQoL dimensions are joint dependent [Ritter et al, 1995; Liang et al, 1986; Rissanen et al, 1996; Aarons et al, 1996].

These favourable results have been primarily identified in small cohorts of patients restricted to either one surgeon or a tertiary centre [Callahan et al, 1994]. Consequently, the generalizability of the findings is restricted to a specific patient group because of the potential selection bias. For instance, those surgeons with more experience were reported to have better patient outcomes than less experienced

surgeons [Lavernia & Guzman, 1995]. This has led some authors to advocate community-based cohorts [Rissanen et al, 1996; Hawker et al, 1998]; however, to our knowledge no studies have prospectively evaluated a community-based cohort of patients receiving joint arthroplasties . It is presumed this type of study design may be more representative of the total patient population and reflective of general practice patterns.

In spite of the positive outcomes for joint arthroplasties, no clear criteria exist for patient selection [NIH, 1994; Callahan et al, 1994]. This assertion is exemplified by a recent survey of orthopaedic surgeons in Ontario [Wright et al, 1995]. Although there was consensus regarding primary reasons for joint replacement, surgeons disagreed on patient characteristics which affected outcomes, practice guidelines, and perceived outcomes. These findings led Wright and colleagues (1995) to surmise that the discordance may be related to inconsistent findings reported in the orthopaedic literature and were reflective of variation in geographic rates [Katz et al, 1996]. Furthermore, they concluded that areas of clinical disagreement should be catalysts for future research of joint arthroplasties.

The effect of age is one patient characteristic which is controversial both in the clinical and research settings. While the majority of patients receiving joint arthroplasties are 60 to 75 years of age, patients over 80 years are less likely to receive joint replacements. The average age for joint replacements has not increased, in spite of an aging population and prosthetic advancements [Katz et al, 1996; Madhok et al, 1993]. In a cohort study of Medicare beneficiaries, Katz and colleagues (1996) reported that receiving a TKA was a function of age. Those patients 85 years or older were less likely to receive TKA than their younger counterparts. Hesitancy to perform this surgery in older patient populations may not be related to age itself, but rather associated with comorbid conditions and post-operative complications.

Limited evidence from small clinical studies have reported favourable pain and functional outcomes of joint arthroplasties in patients 80 years or older, but noted higher complication and mortality rates [Adam & Noble ,1994; Newington et al, 1990; Phillips et al, 1987; Petersen et al, 1989; Hosick et al, 1994]. The generalizability of these findings is restricted because of the descriptive or retrospective study designs used. Findings from more rigorous study designs, case control studies (matched for gender, diagnosis and surgery) [Brander et al, 1997; Zicat et al, 1993], concurred that older patients (80 to 95 years) receiving joint arthroplasties attained similar pain and functional levels as the younger group (65 to 79 years) over a two year follow-up. In contrast to previous descriptive studies, these two studies did not report a higher complication rate in the older group. In light of the limited evidence, much clinical controversy exists with respect to age and the risk of surgery when considering joint replacements. Subsequently, surgeons are confronted with weighing the risks and benefits of joint arthroplasties for older patients. While the benefits and risks of joint arthroplasty have been described in small clinical studies, no study has prospectively

compared these outcomes in a community-based study group. Findings from this type of comparison will have greater generalizability to this patient population.

Another major challenge in the research of joint arthroplasties is determining those significant factors that predict the outcome of joint arthroplasty. Although limited clinical evidence suggests that age and comorbidities affect the outcome, no studies have examined the simultaneous effect of various predictors in a community-based study group. Findings from chart reviews within one hospital indicated that higher body mass index was predictive of greater pain and lower functional outcomes after THA ; however, the authors recognized the limited available data regarding the pain and functional outcomes and questioned the generalizability of these findings [Braeken et al, 1997]. Alternately, MacWilliam and colleagues (1996) did not find that body mass index was a significant risk factor for THA, rather better pre-operative health status, greater number of comorbid conditions, and lower education were factors associated with poor outcomes after THA. Although these two studies have examined medical and demographic data as possible determinants, psychosocial factors such as motivation and social function were reported to be more influential than medical factors or baseline function in determining function after TKA [Sharma et al, 1996].

Because determinants of pain and function are not clearly defined, a subsequent concern is that arthroplasties may be over utilized. Given the significant costs associated with this surgery ($8,000 for in-patients costs), those beneficial and deleterious factors which affect pain and function should be identified.

1.2 Purpose

This study examined the 6 month outcomes of pain, function and HRQoL after total hip and knee arthroplasties in a community-based cohort with respect to joint and age. Furthermore, patient characteristics were explored through multiple regression analyses to identify possible influential factors in predicting outcomes after THA and TKA. Pain and functional differences were examined separately for those receiving hip and knee arthroplasties.

The research questions of this study were:

a) To what extent did pain, function, and HRQoL change after receiving a primary total hip or knee arthroplasty?

b) Did patients 80 year or older attain similar changes in pain, function and HRQoL after joint arthroplasties as patients 55 to 79 years of age?

c) What clinical factors were predictive of pain relief and functional improvement?

This study addressed the following:

a) quantified the magnitude of change seen with pain, function and quality of life 6 months after THA and TKA in a community-based cohort, determined whether the magnitude of change was joint dependent, and determined whether patients attained the norm-based values for quality of life indices.

b) determined whether patients 80 years or older attained similar pain, function and HRQoL outcomes as patients 55 to 79 years of age.

c) identified patient-related factors which were predictive of pain and functional outcomes. A statistical model was developed to predict the change seen with joint-specific pain and function based on the simultaneous effect of significant predictors.

Findings from this study provided insight into the pain and functional gains seen in a community cohort. Moreover, the results should be reflective of general practice patterns and be generalizable to a major proportion of this patient population. In this era of healthcare restructuring and accountability, the results of this study are timely because findings will assist surgeons and clinicians with surgical rationalization and identification of patients who may require further support after surgery.

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CHAPTER 2

LITERATURE REVIEW

Arthritis is a common, chronic disease which primarily affects the elderly population. Osteoarthritis (OA) and rheumatoid arthritis (RA) are two types of arthritis which cause hip and knee joint damage. When joint damage causes intolerable pain and limits normal functional activities, total joint arthroplasty is a viable surgical option. Current surgical rates for joint arthroplasties are rapidly increasing in spite of the lack of quantitative evidence of patient outcomes and selection criteria for suitable candidates [Wright et al, 1995; Gartland, 1988]. Although extensive literature exists with regards to the surgical related issues [NIH, 1994; Callahan et al, 1994], determinants of pain and function for joint arthroplasties have yet to be clearly defined [MacWilliam et al, 1996; Sharma et al, 1996].

This literature review discusses osteoarthritis and rheumatoid arthritis, the associated impairments and disability, and total hip and knee arthroplasties as interventions to provide pain relief and improve function. Concepts of pain, function and health-related quality of life are also discussed within the context of joint arthroplasties along with the challenge of measuring these health components. The final sections of the review examine the effects of disease, age, and comorbid conditions on joint arthroplasties, as well as determinants. A critical review of existing studies and the implications for research are also presented in this final section.

2.0 Osteoarthritis

Osteoarthritis is the leading cause of musculoskeletal disability in the elderly, yet little is known about the natural history of this disease [reviewed in Kirwan & Silman, 1987; Schumacher et al, 1993]. This degenerative disease primarily affects the hands and larger weightbearing joints like the knees and hips. Associated functional disability is variable, although greater functional limitations have been associated with the hips and knees than other joints [Guccoine et al, 1990; Hadler, 1985].

Pathologically, OA is characterized by progressive loss of articular cartilage, appositional new bone formation in the subchondral trabeculae, and osteophytes. Mild synovitis secondary to the joint changes may also occur [reviewed in Schumacher et al, 1993/ Brandt & Fife, 1986]. Clinical features typically consist of joint pain, which is aggravated by activity and relieved by rest, stiffness, joint enlargement and instability, restricted range of motion, and periarticular muscle weakness [reviewed in Schumacher et al, 1993/ Cooke & Dwosh, 1986]. Ultimately, some or all of these features may contribute toward functional limitations.

Unlike RA, OA rarely involves more than four joint groups, yet patterns of joint involvement for the knee and hip are still inconclusive. Osteoarthritis of the knee does not appear to be associated with

development of arthritis in other joints, yet bilateral involvement of the knee is more common than unilateral involvement. Data collected from a national survey, *The United States National Health and Nutrition Examination Survey* (NHANES) found that bilateral OA was more prevalent (5%) than unilateral involvement (2%) in persons 45 to 74 years [Davis et al, 1989]. Conversely, limited clinical evidence suggests that hip involvement is likely associated with other joints such as the spine [Saunders et al, 1979; Brewerton, 1983]. Saunders and colleagues (1979) reported that more frequent radiographic degenerative changes of the lumbar spine were observed in 75 patients with primary OA of the hip as compared to control patients who were matched for age and gender. Findings such as this type of association have led others to speculate that primary OA of the hip is a heterogeneous condition [Peyron, 1986].

Defining the magnitude of OA is a challenge not only because the disease demonstrates considerable heterogeneity, but also the prevalence rates vary with population groups. Until recently, no standardized classification criteria existed to define the severity of OA. Epidemiological data, however, do show certain trends for this degenerative arthritis. Firstly, OA is age-dependent. Prevalence rates of symptomatic OA are estimated from 10% to 20% in those persons 65 to 74 years of age, yet OA is rarely seen in weight-bearing joints before the age of 45 years [Schumacher et al, 1993; Felson et al, 1987].

Secondly, OA is dependent upon the specific joint. Osteoarthritis of the knee is more prevalent than the hip. For example, 10 to 33% of those age 65 to 74 years developed symptomatic OA of the knee [Felson et al, 1987; Schumacher et al, 1993; Davis et al, 1990]; whereas, estimated 4% of people over 65 years have OA of the hip [Croft et al, 1990].

Lastly, OA appears to be gender related. Overall, females are twice as likely to develop OA than their male counterparts irrespective of age [Schumacher et al, 1993; Kirwan & Silman, 1987]; however, this is dependent upon the joint. While women tend to have more joint involvement and experience a greater severity of OA in the hands, knees, ankles and feet; men have greater involvement of the hips, wrists and spine [Peyron, 1986].

The lack of standardized classification has been another problem in defining this patient population. In an attempt to define criteria for the severity of this disease, The American College of Rheumatology developed criteria for classification of OA [Schumacher et al, 1993]. Clinical significance is based on a combination of findings such as the patient's history, as well as, clinical, laboratory, and radiological findings. The sensitivity of the clinical tests for the knee are high (95%), although the specificity is only 69%. Clinical criteria for identifying OA in the hip without a radiograph is reported to be sensitive (86%) but not very specific (75%) [Altman, 1991].

Few risk factors have been definitively recognized as factors for developing OA. Extensive investigations have attempted to identify associations between the prevalence of OA and obesity, major joint trauma, and repetitive joint use. Limited evidence from clinical and population-based studies are contradictory with respect to obesity and OA of the hip [Schumacher et al, 1993; Peyron, 1986; Saville & Dickinson, 1968]. For example, Saville and Dickinson (1968) reported no difference in weight between 121 patients with OA of the hip and the general population when matched for age and gender. Conversely, NHANES data showed an association between obesity and OA of the hip with white women; that is, the age-adjusted relative risk of OA of hips for women who were 50% over their ideal body weight was 2.73 [Hartz et al, 1986].

Alternately, a strong trend of obesity and OA of the knee is supported from population-based studies. Obesity, defined as 50% overweight, was a greater risk factor for women (odds ratio [OR] = 8.98 and 95% confidence interval [CI] = 5.16 to 15.46) than men (OR = 4.46 and 95% CI = 2.88 to 6.91) [Hartz et al, 1986]. This finding suggests that the mechanism of OA in the knee may differ for men and women. In spite of the association between OA of the knee and obesity [Davis et al, 1989; Hartz et al, 1986], few studies have prospectively evaluated this association [Felson et al, 1988]. The Framingham study is one prospective study that followed a population-based cohort for the development of OA of the knee. Adjusting for age and other factors such as physical activity, participants' initial weights upon entering the study were significant predictors for developing OA (relative risk [RR] for men = 1.86 and 95% CI = 1.24 to 2.78; women, RR = 3.16 and 95% CI = 2.23 to 4.48) [Felson et al, 1988].

Limited evidence from clinical and population-based studies suggests major trauma may be another risk factor of OA. For example, those patients with torn anterior cruciate ligaments and post-menisectomies may be predisposed to OA of the knee and experience more severe involvement [Felson, 1990; Cushnaghan & Deippe, 1991]. Data from NHANES reported knee injury was associated with unilateral OA of the knee (left knee: OR = 3.51 and 95% CI = 1.80 to 6.83; right knee: OR= 3.04 and 95% CI = 1.51 to 6.11) [Davis et al, 1989]. Although no definitive relationship has been proven, these specific injuries are purported to cause joint damage of the articular hyaline cartilage, collateral ligaments, or subchondral bone [Davis et al, 1989].

Repetitive joint use of the hip and knee, such as with certain manual labour and athletic activities, may be another potential risk factor, yet no clear relationship has been acknowledged in the literature [Genti, 1989; Peyron, 1986]. Conflicting evidence from epidemiological studies which have examined occupations, such as agriculture, mining, and forestry, and sport activities, such as soccer, running, and wrestling, have not conclusively defined repetitive joint use as a risk factor for the hip or knee [reviewed in

Genti, 1989; Peyron, 1986; Felson et al, 1988]. Subsequently, experts have speculated that the etiology of OA may be multifactorial and not related to one specific activity/occupation [Genti, 1989].

Despite the difficulty of defining this patient population and identifying risk factors, OA is a common disease that can be treated by a variety of approaches. Conservative management of OA consists of patient education, pain relief and maximizing function. When pharmaceutical management and physical therapy are not sufficient to relieve intolerable pain, orthopaedic surgical procedures may be considered. Other indications for surgery are progressive loss of movement, increasing deformity, and progressive loss of function [Schumacher et al, 1993; Cooke & Dwosh, 1986]. There are many surgical options available, but joint arthroplasties are frequently performed when hip and knee joints are severely damaged.

2.1 Rheumatoid Arthritis

Rheumatoid arthritis is a systemic autoimmune disorder which is characterized by symmetrical joint involvement and erosive synovitis of peripheral joints. Most patients demonstrate elevated titre of serum rheumatoid factor. Furthermore, this connective tissue disease may include extra-articular manifestations such as ocular, respiratory, cardiac, gastrointestinal, renal, haematologic, dermalogic and/or neurologic involvement.

The clinical manifestations of RA are joint swelling and tenderness with restricted joint range, muscle shortening, ligamentous instability, and destruction of bone and cartilage [Schumacher et al, 1993; Healey, 1986]. Joint deformity is a major problem and is essentially related to synovitis and pannus formation, subsequent erosion of cartilage, and joint posturing. The course of the disease may be intermittent or progressive. Partial to complete remissions are characteristic of the intermittent course for RA; whereas, the progressive course may have a rapid or slow onset resulting in functional disability.

Prevalence rates of RA range from 1 to 2% of the adult population [Schumacher et al, 1993]. Although the etiology is unknown, the prevalence is higher in women than men (2.5:1) during the typical years of onset (20 to 60 years). Furthermore, prevalence rates increase with age for both genders; 10% of persons 65 years and older have RA [Schumacher et al, 1993].

Prognosis is difficult because of the chronicity and variability of the disease; however, gender, age and disease duration are predictors of disability in RA. Although determinants of function in persons with RA is limited, one population based cohort study (n=2,448) found females 76 years and older were more predisposed to greater disability in terms of activities of daily living (ADL) [Sherrer et al, 1987]. While older females may have greater disability, it was unclear whether this finding could be attributed to co-morbidities associated with age.

Further investigation of a Canadian subset from this same population-based cohort (n=681) showed that 10% of patients with RA remained functionally independent while 13% were completely dependent after approximately 12 years of follow-up [Sherrer et al, 1986]. Perhaps more importantly, the mean disease duration of this particular cohort was 10 years at the beginning of the study. Conversely, Ebernhardt and Fex (1995) examined a small group of patients (n=63) with a mean disease duration of less than a year at commencement of the study and deduced that RA had a good 5-year prognosis with minimal disability. Although few patients had severe functional deterioration (n=9), they found 25% of the cohort had some degree of hip involvement within the first two years. Moreover, knee involvement typically developed in the later stages of RA.

Rheumatoid arthritis not only is a chronic disease causing disability, but is also a disease with increased mortality rates. Whereas persons with OA have similar standard mortality ratios (SMR) to the general population, SMR for persons with RA over 12 and 15 years range from 1.51 to 1.62, respectively [Mitchell et al, 1986; Pincus et al, 1994]. Survivorship is decreased with the usual demographic indicators, older age and male gender, as well as greater disease severity and physical disability. Increased mortality rates of both patient-based and community-based cohorts were correlated with the extent of impairment and disability. That is, patients with more joint involvement and lower functional status were at greater risk of death [Mitchell et al, 1986; Pincus et al, 1994]. The two primary causes of deaths, cardiovascular events (43%) and cancer (13-14%) are similar to the general population; however, infection (9-13%) associated with RA is the third leading cause of death [Mitchell et al, 1986; Pincus et al, 1994]. Other RA related causes of death include vasculitis, rheumatoid lung, amyloidosis, and cervical cord compression. Whereas the cause of death for patients between 50 and 70 years was more likely related to RA, the cause of death for those patients over 70 was similar to the general population [Mitchell et al, 1986].

Conservative treatment for RA consists of patient education regarding rest and activity and pharmaceutical management. While non-steroidal anti-inflammatories (NSAIDs) are the first line of treatment, both systemic and intra-articular steroids are also used. When joint destruction is too great to be managed by conservative methods, orthopaedic surgery is another option.

In summary, OA is a progressive, degenerative joint disease typically occurring in weight-bearing joints such as the hips or knees, whereas, RA is a multi-systemic disease characterized by episodic exacerbations and remissions with progressive disability [Kirwan & Silman, 1987]. Despite the different etiologies, total joint arthroplasties provide pain relief and improved function for these two patient populations.

2.2 Total Joint Arthroplasties

An estimated 63% of knee arthroplasties are performed for joint failure caused by OA and 34% caused by RA [Callahan et al, 1994]; 54% of hip arthroplasties were due to OA and 2-4% due to RA [NIH, 1994; White et al, 1990]. Conversely, the percentage of arthritic patients who actually receive joint arthroplasties is difficult to estimate since prevalence rates for OA and RA populations are vague.

2.2.1 Total Hip Arthroplasty

Total hip arthroplasty (THA) for OA is the most common major elective surgical procedure; approximately 123,000 are performed annually in the United States [NIH, 1994]. Since it was first performed in 1938 by P.W. Wiles [Steinhfield, 1973], the THA has undergone vast improvements with respect to the prosthetic design, materials, and surgical techniques over the past twenty years.

The essential surgical procedure consists of excision of the head and proximal neck of the femur with the removal of the acetabular cartilage and subchondral bone. A metal-alloy femoral prosthesis composed of a stem and small-diameter head is inserted into the femoral medullary canal. The acetabular component, which is constructed of a metal cup with an ultrahigh molecular-weight polyethylene liner, is inserted into the acetabular space of the pelvis. These components are fixed to the bone by either a cement or bony ingrowth into a porous coating on the implant [Siopack & Jergesen, 1995].

The technical challenge of the hip prosthesis is one of durability due to stress. Biomechanically, the hip joint undergoes forces three to five times the body weight during ambulation [reviewed in Neumann, 1989 & Callaghan et al, 1995]. The conventional cement hip arthroplasty, which remains the gold standard of hip replacements, has a longevity of 15 to 20 years. Although the cement technique provides an initial stable interface, future revision is often difficult.

Two other types of prosthesis are the cementless [Engh et al, 1987], and hybrid, which is a combination of cement and cementless components [Harris & Maloney, 1989]. They both provide comparable interface to the cement prosthesis, yet are more amiable to revisions. The cementless acetabular and femoral components were developed primarily because of dissatisfaction with first generation cementing techniques which reported femoral loosening rates from 30 to 40% at ten years [Callaghan et al, 1995]. Although porous coated femoral stems permit bony growth, the rates of thigh pain were reported to be much higher than with cement, 4 to 40% at two to three years.

The etiology of thigh pain is uncertain, yet is presumed to be attributed to the degree of stiffness in the femoral stem component [Callaghan et al, 1995]. Moreover, some authors feel that the success of a cementless prosthesis is not only dependent upon the implant design, but also the bone quality and

surgeon's expertise [Burkart et al, 1993]. The cementless THA is used frequently with a younger, more active patient where revision is more likely to be performed [Cornell & Ranawat, 1986]; the elderly patient is more likely to receive a cement joint replacement because it is less expensive and has a reasonable longevity.

In spite of technical issues, questions also remain concerning indications and contraindications for surgery [Mancuso et al, 1996; NIH, 1994]. Although the decision for joint replacement is primarily motivated by clinical symptoms and radiographic findings, there is no clear consensus in the literature of specific indications. Diagnosis and age are two main considerations for hip arthroplasty. Joint failure caused by OA is the most frequent indication for THA. Other causes include avascular necrosis, traumatic arthritis, certain hip fractures, benign and malignant bone tumours, and arthritis associated with Paget's disease, ankylosing spondylitis, and juvenile rheumatoid arthritis [NIH, 1994].

Early post-operative complications of THA include hip dislocation (1-5%), sciatic nerve injury (0.7%), deep vein thrombi (20% without antibiotic prophylaxis), pulmonary emboli (5%), hematoma/wound infections (3.5%), and intra-operative femoral fractures (3-28%) [NIH, 1994; Siopack & Jergesen, 1995; Callaghan et al, 1995]. Complications may be age related. Previous literature based on small sample groups without comparison of control groups reported greater complications rates than with younger patients [Petersen et al, 1989; Phillips et al, 1987; Levy et al, 1995]. Cardiac complications, hip dislocations, urinary tract infection and mental confusion were early post-operative complications cited in elderly patients receiving THA.

Mortality within 90 days after surgery is 2.5 times greater than in the rest of the first post-operative year after THA [Seagroatt et al, 1991]. Associated mortality within 90 days of surgery is reported to be 15.7 per 1000 for men and 8.4 per 1000 for women. Most deaths were related to cardiovascular events. While peri-operative mortality is not related to race, gender or diagnosis, much controversy exists with age [White et al, 1990; Holmberg, 1992; Whittle et al, 1993]. Data from Medicare administrative database and British health region database indicate that post-operative mortality within 30 to 90 days increases with age [Whittle et al, 1993; Seagroatt et al, 1991]. Conversely, others have reported no age-related differences [Newington et al, 1990; White et al, 1990].

2.2.2 Total Knee Arthroplasty

The knee prosthesis has undergone many modifications over the past twenty years to improve the longevity and quality of movement. Unlike the hip, the knee relies on surrounding contractile and noncontractile structures for its stability. Consequently, limb alignment, ligament balance, and inherent constraint factors pose more of a technical challenge than with hip prosthesis [reviewed in Andriacchi &

Hurwitz, 1997; Cuckler, 1995]. Knee prostheses vary with respect to the compartments replaced, the type of fixation, the prosthetic material and the femoral-tibial constraints. Surgical techniques also vary with respect to the surgical approach, use of instrumentation, prosthetic position, patellar resurfacing, and soft tissue releases such as the posterior cruciate ligament (PCL) [Rorabeck, 1995].

Approximately 120,000 total knee arthroplasties (TKA) are performed annually in the United States [Callahan et al, 1994]. Patient profiles are similar to those patients undergoing THA. Patients are more likely to be over 65 years, approximately 72% are women, and 68% have a diagnosis of OA [Callahan et al, 1994]. As technical improvements are gained, younger patients are receiving TKA with favourable results. In a retrospective patient-based cohort study, Ranawat and colleagues (1989) reported that TKA survivorship after ten years was 96% for 60 patients under 55 years (mean age = 48.7 years) which was comparable to rates reported with older patients [Callahan et al, 1994].

The primary indication for TKA is unrelenting pain which fails to respond to nonsurgical management or less invasive surgical procedures such as arthroscopic debridement, synovectomy, and tibial or femoral osteotomy [Callaghan et al, 1995]. Other indications for TKA include failed osteotomy, avascular necrosis, non-union fractures around the knee joint, and tumour resections. Contra-indications to knee arthroplasty are similar to THA, but muscle strength is also a consideration since adequate strength is required to maintain knee joint stability.

It is unclear whether risk factors of OA are associated with surgical complications. Data are limited and controversial regarding comorbid conditions such as obesity [Smith et al, 1992]. Early complications of TKA include deep vein thrombosis (6.5%), superficial infections (3.9%), peripheral nerve damage (2.1%), pulmonary embolism (2%), and deep infections (1.7%) [Callahan et al, 1994]. One year mortality rate is approximately 1.5% which is comparable to the general population [Callahan et al, 1994].

Restricted knee range of motion (ROM) is another complication that may cause considerable functional limitation [Badley et al, 1984]. A knee range of 0° to 105° is optimal since 65° is required to ambulate and approximately 105° is needed to rise from sitting. Knee mobility after TKA is not dependent upon gender, age, other joint involvement, pre-operative deformity or the use of a continuous passive motion machine [reviewed in Papagelopoulos & Sim, 1997]. Range of motion is dependent on the pre-operative ROM, prosthetic design, post-operative pain and activity. In one retrospective review of 360 patients, knee flexion was reported to improve up to three years post-operatively [Ritter & Campbell, 1987]. Only 35% of the cohort had attained 90° of knee flexion at 6 months; however, this was correlated with pre-operative ROM. Limited ROM after surgery is multifactorial and subsequently, different treatment approaches are needed to attain functional mobility.

When articular adhesions are present, knee flexion may be restricted and manipulation under anaesthesia (MUA) is considered when the knee range is less than 75°. In a retrospective study of 343 patients who underwent TKA, 23% received MUA within two weeks of the initial surgery due to decreased ROM (mean range = 71°) [Fox & Poss, 1981]. Those patients who did not respond well to MUA were patients with RA who had with less than 95° of flexion prior to surgery; all other RA and OA patients who were manipulated had similar ROM at one year to those patients who were not manipulated.

Longevity of TKA ranges from 92 to 98% at ten years and is related to the type of prosthesis [Rorabeck, 1995]. The posterior cruciate ligament-sparing prosthesis has fewer associated complications than any PCL-sacrificing or PCL-substituting prostheses [Callahan et al, 1994] because preservation of the PCL is believed to dissipate interface stresses. The overall revision rate for TKA is 3.8% over a follow-up of 4.1 years. Knee failure is primarily related to aseptic loosening (42%), mechanical failure (29%), or infection (21%) [Callahan et al, 1994].

In summary, THA and TKA have different prosthetic and surgical concerns, yet patient groups tend to be similar. Pain and dysfunction are the primary considerations for joint arthroplasties. The vast majority of this patient population are patients are usually 65 to 74 years in age with OA; however, a smaller proportion of these patients are diagnosed with RA.

2.3 Concepts of Pain and Function

Impairment caused by arthritis is reflected by pain and restricted ROM; whereas, disability is manifested by functional limitations. Limited evidence from clinical investigations have shown that the magnitude of impairment is weakly correlated with disability ($r \leq 0.56$) [Badley et al, 1984; Kantz et al, 1992]; that is, changes in articular surface, loss of joint mobility, muscle weakness, and pain may contribute to functional limitations. Clinically, both patients and rheumatologists agree that pain and functional activities are primary concerns in RA and OA [Yelin et al, 1987; Bellamy & Buchanan, 1986].

Pain is a primary clinical feature of arthritis and is a complex response to joint degeneration. Although the exact mechanisms for pain are unknown [Dubuisson & Melzack, 1976], physical stress and reactive responses such as secondary inflammation, and neurogenic immobilization of the joint contribute towards the pain. The perception of pain is also complex and is influenced by many factors, including the patient's personality, ethnic background, and associated psychological status [Bradley, 1985]. Thus, pain is multifactorial and greatly varies between and within individuals.

Pain in patients with OA is usually activity-related. Walking and climbing stairs are frequently cited as painful activities. Static pain is related more to the severity of the disease and is preceded by pain with activity [Bellamy & Buchanan, 1986]. Conversely, pain due to RA occurs both at rest and on activity.

Women have lower pain thresholds than men; however, when matched for gender, pain thresholds tended to be higher in patients with OA than RA [Gerecz-Simon et al, 1989; Callahan et al, 1989].

While pain relief is a primary goal of treatment for arthritis, investigations have shown that pain relief attained from joint arthroplasties may not necessitate normal function [Long et al, 1993]. Clinical evidence from a small patient group (n=18) demonstrated that in spite of pain relief after THA, abnormal gait patterns persisted two years after surgery [Long et al, 1993]. This led the authors to surmise that success of THA not only is dependent on pain relief, but is also related to recovery of other impairments such as muscle strength and flexibility [Long et al, 1993; Roush, 1985].

Function refers to a person's ability to perform activities which are considered normal for that individual [McDowell & Newell, 1996; Bowling, 1995]; however, the use of function as a health term is ambiguous and has led to conceptual and semantic differences. Function is not merely a measure of physical capability. It is generally agreed that function is a global measure which is comprised of a complex interaction of physiological factors, psychosocial components, socio-economic status and environmental factors.

Extensive evidence from longitudinal and cross-sectional investigations have established an association between arthritis and functional limitation [Sherrer et al, 1986; Badley et al, 1984; Yelin et al, 1987]. Further investigations reveal that the disability related to OA is more task specific; whereas, a broad spectrum of restrictions are reported with RA. In *The Framingham Study*, OA of the knee accounted for a significant amount of disability when controlling for co-morbidities in a community-dwelling cohort (n=1416) [Felson, 1990]. Although OA does not affect all functional activities, 37.5% of those participants who had OA of the knee were dependent in one or more ADL as compared to 30% who did not have arthritis [Guccione et al, 1990]. Requiring assistance for activities such as cooking did not differ from those without OA (OR = 0.58 and 95% CI = 0.13 to 2.50) as compared to stair climbing. Participants who had OA of the knee were 3.72 times (95% CI = 1.75 to 7.93) more likely to require assistance when climbing stairs than those who did not have arthritis.

Persons with RA have a wider range of functional limitations than persons with OA. In a comparison of patients with OA and RA with age and gender matched control group, patients with RA reported limitations of a wider group of instrumental activities of daily living (IADL) such as shopping and household chores than the other groups [Yelin et al, 1987]. Although this study did not examine ADL, another comparison study found that patients with RA reported more difficulty performing ADL than patients with OA when matched for age, gender, disease duration and education [Callahan et al, 1989]. Although the two groups differed to the type of functional activities that were limited, the primary concerns for both groups are limited functional capacity.

2.4 Concepts of Health-Related Quality of Life

Health-related quality of life has been increasingly used as an outcome in clinical trials to measure the effectiveness of interventions. This increase has been reflected in a parallel increase of HRQoL outcomes used to evaluate joint arthroplasties. While particular emphasis has been directed towards defining the content of HRQoL instruments, relatively little research has examined the inherent complexities of the construct for quality of life. This has led some experts to propose an array of theoretical frameworks to define health-related quality of life.

In spite of the need to measure HRQoL, the relationships of clinical variables and their ability to measure HRQoL have not been explicitly explored. Causal relationships between clinical variables and the domains of HRQoL will encourage the use of HRQoL measures. Interpretation of these relationships requires the conceptualization of different models of health.

The concept of health is nebulous. Terms used to define health can be positive states such as 'wellness' and 'normal', or negative states like 'disability' and 'illness'. Moreover, the concept of perfect health is an abstract notion which could be interpreted as the best imaginable health; whereas, death epitomizes negative health state. Although few would disagree that death is the minimal level of health, other states of illness such as paralysis may also be interpreted as minimal health status. While these terms do not define health, *per se*, they are subjective interpretations of health. The most widely accepted definition of health is the 1948 World Health Organization's (WHO) definition as 'a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity' [Patrick & Erickson, 1993]. This definition encompasses the notion of overall positive well-being but consequently generates ambiguity regarding interpretation. Although this definition lacks specificity, it does envelops the concept of health status which in turn includes physiologic factors, functional states, and perception of well-being. In the context of healthcare, health status, functional status, and health-related quality of life are three concepts that have been interchanged.

Quality of life is a broad concept which has traditionally not only included health, but also social and economic aspects. Because of this global definition, research in the health sector has focused on the health related aspects of quality of life which encompasses the WHO' s definition of health, as well as emphasizing the subjectivity and multidimensionality components. Health-related quality of life is value laden with respect to the quantity and quality of life as affected by impairments, function, perceptions and social function that are influenced by disease, injury, treatment or policy [Patrick & Erickson, 1993].

Research in the area of HRQoL has particularly focused on the measurement of HRQoL. There have been two fundamental types of measures for HRQoL: generic instruments and disease specific

instruments. Generic health instruments include single indicators, health profiles and utility measures. These measures attempt to provide a summary of HRQoL by measuring the overall health status. A major advantage of this type of measure is that it provides a global measure which can be applied to an array of populations. Because of the broad scope, sensitivity of this type of measure is less than the sensitivity reported with specific instruments [Bombardier et al, 1995; Kantz et al, 1992]. Unlike generic health measures, disease-specific measures focus on the area of prime interest such as osteoarthritis of the hip or knee. At the expense of a comprehensive health evaluation, the specific instruments tend to be more responsive to change within that defined domain. One challenge of measuring HRQoL, particularly in joint arthroplasties, is to select a measure(s) that is responsive to change. Research in this area has shown that both generic and disease-specific measures are needed to thoroughly evaluate the effect of joint replacements [Bombardier et al, 1995; Kantz et al, 1992].

While considerable research has been directed towards the development and validation of HRQoL measures, relatively little research has examined the relationships of these conceptual models. In the context of a chronic disease such as arthritis, a multitude of factors interacts to prompt a patient to seek medical attention to alleviate pain or dysfunction. An underlying preposition is that joint destruction caused by arthritis is the catalyst of pain and dysfunction. Research in arthritis has shown that the effects of pain and dysfunction are far reaching [Laupacis et al, 1993; Rissanen et al, 1995]. While pain, functional impairments, and disability are prime issues of arthritis and joint arthroplasties, they may be regarded as components of the overall health status. Functional clinical measures such as walking speed and muscle strength have reported improvements after joint arthroplasties [Wang et al, 1998; Wykman & Olsson, 1992; Finch et al, 1998], yet relatively little research has determined the extent that HRQoL is affected after joint arthroplasties. Not only can the physical domains be affected by pain and dysfunction, but also the mental, social, and health perceptions dimensions.

One HRQoL model proposed by Wilson and Cleary (1995) attempts to establish a continuum of biologic, social, physical and psychological factors (Fig. 2-1). This model consists of five components: biological and physiological factors, symptoms, functioning, general health perceptions, and overall quality of life. The authors also recognize the involvement of emotional and psychological factors at each level. Moreover, this HRQoL model attempts to combine biomedical and quality of life models.

Patients may initially seek medical attention because a) they want to alleviate their symptoms, b) they are limited in certain activities, or c) they are worried something is seriously wrong. For patients with arthritis, they most likely will have unrelenting pain or difficulty performing an activity. The physician or surgeon may focus the assessment on biologic factors such as the degree of joint destruction. Empirical studies have shown the complexity of the relationship between biologic and symptom factors. For example,

many persons in the HANES study who demonstrated considerable radiographic evidence of knee arthritis, did not have symptomatic knee pain [Felson et al, 1987]. While symptoms such as knee pain may be manifested in limited function, other factors such as motivation and personality influences how a person functions physically, emotionally, and socially. This may explain why two patients with similar osteoarthritic hip conditions present differently.

When considering a suitable candidate for joint arthroplasty surgery, a surgeon's assessment more often is based on the biologic variables such as radiographic findings, symptoms and dysfunction. Concerns expressed by a patient, however, may centre on symptoms, function, general health perception, and quality of life. At each stratum of this model there is an increase in the number of factors not controlled by the clinician and this may be part of the difficulty in measuring the effectiveness of an intervention such as joint arthroplasty with HRQoL outcomes.

When a patient undergoes a joint replacement, this intervention focuses solely on the biologic problem, a destroyed joint. Later, rehabilitation addresses the biologic, symptoms and functional levels: reduce swelling, pain management, and ambulation. Currently, the effect of joint arthroplasty on HRQoL is not clearly understood. One goal in determining the effectiveness of joint arthroplasties is to identify a change in HRQoL. A subsequent goal is to determine the relationship between the surgery (biologic level) and the overall health status. To achieve this goal, the evaluation of joint arthroplasty should consider all levels of function and consequently, use both disease and generic health outcomes. Research has only now begun to recognize the effect of joint arthroplasties on HRQoL, but it has been evaluated in select patient groups. It is unclear whether this relationship is indicative of the joint arthroplasty population. Another challenge is to measure outcomes at various levels as defined within the model and develop a causal model that can explore the relationships between these components.

While the model by Wilson and Cleary (1995) proposes the interrelationship of biomedical and quality of life models, the inter-relationships are likely multi-directional having both direct and indirect effects. Thus, this model presents a continuum of various components that may provide a suitable framework to explain the relationships of certain variables (socio-demographic, medical, peri-operative) on the pain, function and overall health status of joint arthroplasties.

2.5 Generic and Disease-Specific Health Measures

Patients with arthritis frequently cite pain and functional limitations as primary problems, yet the quantitative evaluation of pain and function is an inherently complex process. Traditionally, health and quality of life of patients with arthritis were measured by function, that is, how well a person performed in his/her environment [Bowling, 1995]. Clinical measures such as range of motion, radiologic evaluation, and

laboratory parameters do not predict function with certainty. Not only are there multiple factors interacting with each other, but also great variability exists between and within patients. Perhaps more importantly, pain and function are highly relative which makes measurement a challenge.

Many measurement issues need to be considered before selecting a measure to evaluate joint arthroplasties. One issue concerns the type of instrument best suited to measure pain and function. Experts advocate the use of both generic and disease-specific measures when assessing joint arthroplasties since both have advantages and disadvantages [Liang et al, 1982].

Generic health status measures are global instruments that attempt to measure the overall physical and psychosocial health [Patrick & Deyo, 1989]. They are capable of measuring health in a specific condition, as well as measuring other conditions affecting health status. Because the generic measure is multi-dimensional, complications not specifically related to the condition are more readily identified than with a disease-specific measure [Kantz et al, 1992]. Furthermore, comparisons across other conditions and populations can be made with this type of measure.

At the expense of being comprehensive, generic instruments are faced with the dilemma of precision. Limitations of generic measures typically concern content validity and sensitivity for a given disease. For instance, limitations of the SF-36 have been cited with chronic disabilities such as arthritis because of the brief list of physical disabilities [Bellamy et al, 1995]. Dawson and colleagues (1996) reported that a generic health measure is useful to identify other problems that may interfere with the recovery after joint replacement surgery; however, a disease specific measure is more appropriate to identify pain and function related to the joint arthroplasties.

A disease-specific measure is intended to evaluate the specific condition and the associated patient problems. This type of measure generally has better sensitivity to a given condition than a generic measure and subsequently, is better at detecting effects of an intervention [Bombardier et al, 1995; Dawson et al, 1996; Kantz et al, 1992]. For instance, a disease-specific measure was sensitive to pain and knee function of both knees in elderly patients who received TKAs; whereas, a generic measure had poorer discrimination capabilities [Kantz et al, 1992]. Inasmuch as a disease-specific measure, such as the WOMAC, discriminated better among patients with knee problems, a generic measure, SF-36 discriminated better with general health status and comorbidity problems of this clientele [Bombardier et al, 1995]. Consequently, the use of generic health measures is recommended in measuring health-related quality of life items in arthritis and joint replacement surgeries, but should be supplemented with disease-specific measures [Bombardier et al, 1995; Dawson et al, 1996; Kantz et al, 1992].

Another measurement issue relates to whether self-report instruments such as disease-specific and generic measures reflect the true functional performance. Clinical measures of functional performance address motor capacity, manual ability, and self-care abilities. Although a patient's functional capacity may be different from the actual performance, self-reported measures of function and general health do not appear in be inferior with respect to sensitivity of change, reliability and validity of clinical performance measures [Myers et al, 1993]. Supporting evidence has also been reported in elderly persons residing in the community [Kivela, 1984], and elderly patients [Harris et al, 1986]. Nevertheless, both self-report and clinical performance measures are incapable of distinguishing unmotivated from incapable patients and this problem may reflect inaccuracies observed with functional measurements.

2.6 Measures

2.6.1 Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index

The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index is a disease-specific measure designed to measure disability of the osteoarthritic hip and knee [Bellamy et al, 1988(a); Hawker et al, 1995]. This self-administered questionnaire consists of three dimensional components: pain (5 questions; subscore range = 0-20), stiffness (2 questions; subscore range = 0-8), and physical function (17 questions; subscore range = 0-68) (Appendix A). Each item uses a five point Likert scale. Aggregate scores are calculated for each dimension by summing item scores and then transforming the subscale scores to a range from 0 to 100 points. Equal weighting for each item by simple summing is recommended for the WOMAC [Bellamy et al, 1991].

The development of the WOMAC was based on identification and prioritization of symptomatology defined by patients with OA of the hip and knee. [Bellamy & Buchanan, 1986]. Subsequent validation and reliability testing included studies examining hip and knee arthroplasties [Bellamy et al, 1988(a)] and pharmacologic interventions [Bellamy et al, 1988(b)].

Reliability testing, the consistency of a measure to produce identical results, yielded high values with the WOMAC. Test-retest reliability over a one week period was measured in patients with hip and knee pain due to OA. Reliability coefficients measured by Kendall's tau c statistics, a measure of association for ordinal variables, were adequate (0.48 to 0.68) [Bellamy et al, 1988(a)]. Internal consistency of the WOMAC was also examined with the same study population. This form of reliability measures the degree to which a set of items measures the same characteristics and is generally described by a Cronbach's alpha. Values can range from 0 to 1, but coefficients equal or greater than 0.80 were regarded as acceptable [Bellamy et al, 1988(a)]. Coefficients for all three dimensions of the WOMAC were greater than 0.85. Given

the high internal consistency coefficients and sensitivity, the authors inferred that lower test-retest values were due to the fluctuating status of the patient groups.

The degree to which the WOMAC measures what it is intended to measure: pain, stiffness and function, was defined by validity testing based on construct validity using Pearson's correlation coefficients. Because no gold standard existed, the WOMAC was compared to four other health measures: modified Doyle Index, Lequesne Index, Bradburn Index, and the McMaster Health Index Questionnaire [Bellamy et al, 1988(a)]. The construct validity of pain, stiffness and physical function was supported by statistically significant ($p < 0.05$) correlation to the other scales' dimensions for OA patients undergoing joint replacements [Bellamy et al, 1988(a)].

Responsiveness or the ability of the WOMAC to detect change was also tested in a randomized control trial design of osteoarthritic patients receiving NSAIDs. All three dimensions were reported to be statistically significant ($p<0.05$) during six weeks of active treatment [Bellamy et al, 1988(b)]. Another study investigating the functional outcome of patients with TKA's showed that the WOMAC had better discriminant validity among OA patients with varying severity of knee problems than a generic health measure, the SF-36 [Bombardier et al, 1995]. Conversely, the WOMAC could not discriminate general health and co-morbidities as well as the SF-36.

In summary, the WOMAC has proven reliability and validity within the OA population. The patient relevant outcomes also demonstrate clinical sensitivity, although comparisons with other multi-dimensional measures are limited. Despite the extensive evaluation of the WOMAC, reliability and validity of this measure have yet to be proven within the RA population. Although this may be a limitation, it is presumed that the WOMAC will adequately describe joint specific pain, stiffness, and function of the RA population.

2.6.2 Generic Health Measure: SF-36

The generic health status questionnaire, *SF-36 Health Survey* (SF-36), is a 36 item questionnaire which was designed as a generic indicator of health status for clinical use, research, population surveys and evaluative studies of health policy [Ware & Sherbourne, 1992; McHorney et al, 1994; Stewart et al, 1988]. It was designed for self-administration, telephone administration, or administration during a personal interview. Subsequently, it has been used for comparisons of different populations and for evaluation of a wide variety of conditions [McDowell & Newell, 1996; McHorney et al, 1994] including arthritis [Stucki et al, 1995] and joint replacements [Bombardier et al, 1995; Bayley et al, 1995; Coleman et al, 1996].

The SF-36 incorporates physical, social and mental concepts of not only positive aspects of health, but also negative health. This questionnaire comprises one multi-item scale measuring eight health dimensions: emotional role function (question 5-3 items), physical role function (question 4-4 items),

physical function (question 3-10 items), mental health (question 9-5 items), vitality (question 9-4 items), general health perceptions (question 1 & 11- 5 items), social functioning (questions 6, 10), and bodily pain (questions 7, 8) (Fig. 2-2). A Likert scale is used to score the responses. A scoring algorithm for each dimension is calculated to produce eight subscale scores. The scoring for each scale ranges from 0 to 100 with higher scores representing better health. Norm data from the general U.S. population for seven age groups, gender, and 13 medical conditions are also available for each of the eight dimensions [Ware & Sherbourne, 1992].

Because a profile of eight subscales may likely be difficult to interpret when the effect varies across all dimensions, two summary scores were developed [Ware et al, 1994]. The physical component summary (PCS) and the mental component summary (MCS) were derived from factor analyses of the eight scales and standardized using norm-based methods. Summary scores describe the overall changes in HRQoL, but do not capture the smaller changes within the specific domains. These summary scores are reported to account for more than 80% of the reliable variance in the eight subscales.

The two component summary measures were calculated from the means, standard deviations and factor score coefficients of each of the eight scales which were derived from the general US population. A linear T score transformation method was used in order that both summary measures had a mean of 50 and a standard deviation of 10 in the general American population. While this scoring contrasts the scoring of 0 to 100 used in the eight scales, the advantages for the standardization and norm-based scoring of these two component summary measures are two-fold. First, the scoring permits direct comparison between the two summary scores and further, the scores have a direct interpretation to the distribution of scores in the general population. In addition to reducing the eight scales to two summary measures, the summary scores eliminate ceiling and floor effects and provide a greater number of defined levels.

Reliability and validity of the SF-36 have been extensively examined in both healthy and patient populations. High alpha coefficients for internal consistency of the 8 dimensions and the summary scores have been reported from many studies [Kantz et al, 1992; McHorney et al, 1994; Brazier et al, 1992; Ware et al, 1994]. Cronbach's alpha has generally exceeded 0.80, except for social function scale (r= 0.76) [Brazier et al, 1992; Lyons et al, 1994; Ware et al, 1994]. Test - retest reliability for a patient-based population over two weeks period were highly correlated (r> 0.80) except for social function (r= 0.60).

The construct validity is good and when compared with other health instruments (*Sickness Impact Profile, Quality of Well-being Scale, Nottingham Health Profile*), was more sensitive to change of community dwelling elderly persons, elderly patients, and patients with joint replacements [Andresen et al, 1995; Brazier et al, 1992; Stucki et al, 1995]. Findings from a retrospective study of patients with TKAs indicated that the SF-36 was less sensitive to knee pain than a disease-specific measure, yet was

comparable with knee function [Kantz et al, 1992]. Furthermore, the pain score from the SF-36 reflected the combined effects of the primary knee pain and other sources of pain. Other similar evidence indicated that the SF-36 could better discriminate comorbidities than the WOMAC for pain, physical function and overall score [Bombardier et al, 1995]. Although overall health perception was determined by different factors in the elderly (70+ years) than younger patients (50 to 69 years), the SF-36 was reported to be a sensitive measure in evaluating quality of life in the elderly undergoing elective surgery (Mangione et al, 1993). The predictive validity of this measure to predict outcomes for joint replacements remains unanswered [McGuigan et al, 1995].

Although the advantages of the SF-36 when compared to other generic instruments are its brevity and comprehensiveness, limitations have been identified with validity pertaining to chronic disabilities, the severely ill, and elderly persons. Criticism has been directed towards its use with the arthritic population because of the brief list of physical disabilities emphasizing general activities rather than incorporating IADL activities. Nor does the SF-36 include evaluation of upper extremity function [Bellamy et al, 1995]. Moreover, other indirect issues that are related to arthritis such as health distress, sexual function, cognitive function and sleep disorders were not addressed in the SF-36.

Secondly, some experts have questioned the responsiveness of scores to changes in health status with certain populations. Concern about potential floor effects with severely-ill patients has been expressed [Ware & Sherbourne, 1992], yet the SF-36 detected changes of general health among patients with joint arthroplasties better than other generic and disease specific measures [Coleman et al, 1996; Hawker et al, 1995]. Analogously, ceiling effects were reported with healthy elderly people residing in the community [Andresen et al, 1995].

Furthermore, experts have questioned the responsiveness of the two summary scores. Although the basis of the theoretical framework presumes that mental and physical functioning are two distinct aspects of health, Simon and colleagues (1998) reported the physical summary score was not reflective of changes reported in the physical health subscales of the SF-36 when evaluating mental health interventions. They concluded this was most likely due to the computation of summary scores treating mental and physical health as distinct phenomena and express caution in the sole use of the summary scores.

Lastly, the appropriateness of the SF-36 in the elderly has been questioned by some investigators [Hayes et al, 1995; Lyons et al, 1994; Brazier et al, 1992]. A high percentage of missing data has been reported in the elderly population [Hayes et al, 1995; Brazier et al, 1992]. For example Hayes and colleagues (1995) reported missing data in 70% of 122 respondents who were 75 years of age and older,

yet they surmised it was most likely related to visual or writing problems. To avoid this dilemma, some elderly participants may require assistance when completing this questionnaire.

2.7 Pain, Function and Health-Related Quality of Life Outcomes

Improvement of health-related quality of life after joint arthroplasties is supported by retrospective and prospective patient based cohort studies. The greatest gains have been identified within the first 3 to 6 months with more gradual functional improvements occurring one to two years after surgery [Laupacis et al, 1993; Kirwan et al, 1994; Bayley et al, 1995; MacWilliam et al, 1996; Wiklund & Romanus, 1991; Ritter et al, 1995; Sharma et al, 1996; Braeken et al, 1997].]. For example, using a generic health instrument, the *Health Status Questionnaire* (HSQ), to measure pain and function, 84% of 442 patients receiving THAs reported improvement of pain and 76% reported improvement in function 6 months after surgery [MacWilliam et al, 1996]. In a smaller patient-based study (n=45), functional improvements were reported with stair climbing, yardwork and getting in-out of car after joint arthroplasties [Roush, 1985].

Further support of improvement was documented in a meta-analysis of TKAs; 75% of patients (n=1938) reported no pain and only 1.3% described their pain as severe after four years [Callahan et al, 1994]. Although pain is a primary indication for surgery, only 26 studies (17%) reported pain as an outcome. Very high rates were also reported with functional outcome after four years, 89.3%, yet no functional ratings were reported within a year after surgery. In this same meta-analysis, differences in health-related outcomes were identified with the type of prosthesis used for knee arthroplasties; higher global scores and less complications were identified with PCL- sparing prosthesis [Callahan et al, 1994]. No statistical differences have been identified with different hip prostheses.

Although the success of joint arthroplasties are reported in pain relief and functional improvements, other areas of health improve post-operatively. In a review of the literature, eleven studies were identified that examined health-related quality of life in total hip or knee arthroplasties. All except one study [Hawker et al, 1998] were hospital or surgeon based. Six of these studies followed patients within a year of their surgeries [van Essen et al, 1998; MacWilliam et al, 1996; Ritter et al, 1995; Bayley et al, 1995; Laupacis et al, 1993; Wiklund & Romanus, 1991]. The other studies follow-up times ranged from 2 to 20 years [McGuigan et al, 1995; Rissanen et al, 1996; Hilding et al, 1997; Franzen et al, 1997; Hawker et al, 1998].

Among those studies that examined HRQoL within a year of surgery, improvements with mobility, social interactions and psychological well-being were reported [van Essen et al, 1998; Laupacis et al, 1993; Wiklund & Romanus, 1991]. Interestingly, these improvements were not reflected in improvements of general health perception [van Essen et al, 1998; Bayley et al, 1995; Ritter et al, 1995]. Although improvements in HRQoL are reported in earlier studies, these gains are not comparable to health control

groups. Patients did not attain similar levels as health reference groups in pain, mobility, sleep and social after undergoing THA [Franzen et al, 1997; Rissanen et al, 1996]. Furthermore, patients with TKA did not attain levels with pain, mobility, sleep, and energy [Rissanen et al, 1996].

2.8 Disease and total joint arthroplasties

In spite of articular and systemic features of RA, evidence from both retrospective and prospective data indicate outcome of joint arthroplasties are no different than patients with OA. White and colleagues (1990) compared the short-term morbidity and mortality of 721 patients with RA to 8,859 patients with OA receiving THAs. They reported that RA surgical candidates tended to be younger women (58.1 $\pm$ 15.2 years) as compared to their OA counterparts (68.5 $\pm$ 10.2 years). Adjusting for age, no differences were identified between OA and RA patients concerning mortality rates within 90 days of surgery and hospital length of stays. Rheumatoid arthritic patients had significantly higher rates of wound infection (1.7%) and dehiscence (0.6%), which may be associated with the use of oral corticosteroids [Garner et al, 1973]. Conversely, RA patients had a lower rate of thromboembolic events (0.3%) than OA patients (1.2%) [White et al, 1990]. Although little differences were cited between these two patient populations, surgical procedures, prosthetic type and functional status were not examined in this study.

Further evidence from prospective data indicate that the functional outcome of RA patients receiving joint arthroplasties are favourable. Longer follow-up of 54 patients receiving joint arthroplasties showed that mobility improved 10% after 6 months from pre-operative status; however, those patients with lower pre-operative mobility scores achieved a lower post-operative level than those patients who were less disabled [Jonsson & Larsson, 1991].

2.9 Age and total joint arthroplasties

Although there is no clear consensus for indications of surgery, age is one consideration. Approximately two-thirds of total joint arthroplasties are performed on patients over 65 years of age [NIH, 1994]; however, those patients under 80 years of age are more likely to receive joint arthroplasties despite the increasing prevalence of arthritis with age. A population-based study of American hospitals reported that the odds of receiving a TKA were greater for patients 70 to 79 years of age than for those patients 80 years or older [Katz et al, 1996]. Furthermore, patients 85 years and older had a 41% less chance of receiving a TKA than those patients 65 to 69 years of age.

The possible reasons for this age discrepancy remain purely speculative at present, since most studies that examined patients 80 years and older were descriptive studies (Table 2-1). There are a few presuppositions for this hesitancy to perform surgery in older populations. Firstly, surgical complications and mortality rates are considered to be age related. Previous literature which have specifically evaluated

patients 80 years of age or older indicate that older patients experience more complications higher mortality rates, irrespective of comorbid conditions and [Jacobsson et al, 1991; Adam & Noble, 1994; Newington et al, 1990; Phillips et al, 1987; Petersen et al, 1989]. The consensus among these studies is that patients 80 years and older experience more complications and prolonged hospital stays [Jacobsson et al, 1991; Newington et al, 1990; Boettcher, 1992; Phillips et al, 1987; Hosick et al, 1994].

Frequently cited post-operative complications for the octogenarian group were acute dislocations (hip), cardiac and pulmonary complications, urinary retention, acute post-operative confusion, limb edema and deep venous thrombi. A review of 356 patients undergoing THA reported those patients 73 years and older were 3.9 times more likely to develop serious complications during their hospital stay [Greenfield et al, 1993]. Petersen and colleagues (1989) reported that 13 of the 27 patients receiving THA experienced early post-operative complications and inferred this was greater than published rates in younger patient populations. In spite of the higher complication rates, these findings were reported in a small sample group with no comparison group. Alternately, Brander and colleagues (1997) compared patients 80 years or older to a control group matched for surgical type, diagnosis and surgeon. They reported that, although the older group experienced greater comorbid conditions, they were at no greater risk for death or serious complications than the younger patient group (65 to 79 years). Thus, previous published findings regarding age and complications after joint arthroplasties remains inconclusive.

Secondly, a greater number of comorbid conditions is an independent risk factor for complications [MacWilliam et al, 1996] and older patients are more likely to have more comorbid conditions. Data from the *Supplement on Aging of the National Health Interview Survey* reported that elderly persons residing in the community have an average of 2.68 comorbid conditions (range 0 to 13) [Verbrugge et al, 1989]. The number of comorbid conditions is age-related for both genders, although women 80 years or older have the higher prevalence of comorbid conditions. Furthermore, the number of comorbid conditions is directly associated with greater functional limitation [Guccione et al, 1994]. Data from a longitudinal study, *The Framingham Study*, found that 318 of 1769 (18.9%) people residing in the community had OA of the knee; 50% of those reported at least one other condition.

Thirdly, the quality of life for the older patient undergoing total joint arthroplasties has not been examined because it may be perceived to be limited. The evidence for overall health status improvement in the older patient population is limited since most studies analyze patients of widely differing ages as a single entity and use clinical rating scales. Brander and colleagues (1997) reported that improvement in pain as measured by clinical rating scales (*Harris Hip Score* and *Hospital for Special Surgery* score) was comparable to a younger control group; however, recognized the potential of reporting bias with this type of measure. These findings concurred with Zicat and colleagues (1993) who reported no pain or functional

differences with TKA between octogenarian patients and a younger comparison group. An extremely high percentage of older patients reported complete pain relief at rest and on activity (98% and 87%, respectively). However, these high success rates may be partially explained by the use of clinical (*Hospital for Special Surgery Knee Rating*) rather than patient-based measures. Other studies that examined patients 80 years or older have also reported 'good' to 'excellent' results with pain and function using clinical rating scales [Levy et al, 195; Hosick et al, 1994]. To our knowledge, no comparative study has prospectively measured the quality of life in patients 80 years or older.

2.10 Comorbid conditions and joint arthroplasties

A comorbidity is a distinct additional clinical entity that has existed or that may occur during the clinical course of a disease [Feinstein, 1970]. Failure to classify and analyze comorbid conditions in clinical research can create statistical problems because of the unrecognized bias. The significance of comorbid conditions as potential sources of confounders have been recognized with a variety of medical conditions [Charlson et al, 1987]. Measurement of comorbid conditions, however, has not been clearly established within the orthopaedic or rheumatology literature. What constitutes comorbid conditions and how to measure them remain unresolved issues within these areas of research (Table 2-2).

While differences of measurement exist in the literature, some trends can be identified. First, comorbid conditions are age related; with increasing age, a greater number of comorbid conditions are likely to exist. A high prevalence of comorbid conditions in community-dwelling elderly persons was delineated by the *1984 National Health Interview Survey* (NHIS) which examined American civilian noninstitutional persons aged 55 and older regarding chronic conditions [Verbrugge et al, 1989]. Sixty-three percent of this population reported two or more chronic conditions while only 16.4% had no chronic conditions. Perhaps more importantly, arthritis was the most prevalent chronic condition (43.7%) and the leading pairs of chronic conditions were arthritis and high blood pressure (21.1%) and arthritis and hearing impairment (14.7%).

Second, the number of comorbid conditions is directly associated with functional limitations. Verbrugge and colleagues (1989) looked at the pattern of disability and comorbidity in the NHIS cohort. They compared physical limitations to the number of chronic conditions and found that as the number of chronic conditions increased, so did reported disability almost exponentially. Furthermore, at a high number of chronic conditions (10), the rise in disability ceased, or rather, additional problems did not affect disability of the very ill persons.

While comorbid conditions are well recognized as clinically important factors for surgery, no standardized measure of comorbid conditions has been promoted to evaluate total joint arthroplasties. Subsequently, studies that have reported comorbid conditions have typically used a predefined checklist of

certain medical conditions and counted the number of comorbid conditions. Limited evidence from cross sectional and longitudinal studies verify the number and type of comorbidities affect the long-term recovery of THAs [MacWilliam et al, 1996; Munin et al, 1995; Greenfield et al, 1993; Kantz et al, 1992]. Retrospective findings reported by Greenfield and colleagues (1993) reported that the number and type of comorbidities are significant predictors of function with THAs after one year. Interestingly, visual problems and chronic back problems were conditions that affected physical function after THAs [MacWilliam et al, 1996]. Cross-sectional data also indicate back problems are associated with physical function of patients after TKAs [Kantz et al, 1992].

Comorbidity scales have customarily been designed to predict mortality in acute care settings. Some have attempted to classify comorbid conditions by weighting the severity of comorbidities with respect to mortality. For example, the Charlson Co-morbidity Index is one of the few validated indices. Although it was designed to classify the prognostic effect of comorbidity in longitudinal studies, it was validated from an inception cohort of medical patients admitted to acute care setting [Charlson et al, 1987]. This type of comorbid indices is not standardized with respect to functional activities, which was exemplified in a study of risk factors for pain and functional outcomes after THA. MacWilliam and colleagues (1996) used the Charlson Co-morbidity Index to measure comorbid conditions in patients with THA and reported a skewed distribution of comorbidity scores. They decided not to use this index to weight comorbid conditions in a patient population undergoing joint arthroplasties since these patients are relatively healthy and are undergoing elective surgery.

Comorbid conditions are well-recognized as important factors in determining surgical outcomes, yet the necessity for standardized methods of defining and recording comorbid conditions is acknowledged within the joint arthroplasty literature [Imamura et al, 1998].

2.11 Determinants of Pain and Function

In spite of the improvements reported with joint arthroplasties, no clear prognostic factors have been identified in the literature. The number of comorbid conditions is one factor that affects 6 month outcome of THAs; a greater number of comorbid conditions was associated with higher pain scores and lower function [MacWilliam et al, 1996]. Another prognostic factor identified in this same study was preoperative health status. Those patients with lower pre-operative health scores as measured by a generic measure (HSQ), reported higher pain scores and lower function. In a retrospective chart review, Braeken and colleagues (1997) found that a higher body mass index was also related to greater pain and lower functional outcomes of THA. Although the majority of studies have examined medical and demographic data as possible determinants, psychosocial factors such as motivation and social function were reported to

be more influential than medical factors or baseline function in determining function after TKA [Sharma et al, 1996].

2.12 Limitations of Total Joint Arthroplasty Studies

Interpretation and comparison of joint arthroplasty studies have been a challenge because of three basic methodological limitations: poorly defined patient groups, poor validity of outcome measures, and less rigorous study designs. Because of these limitations, the potential for bias may have been increased and validity of the results questionable.

One commonly expressed limitation has been poorly defined study groups; patients of widely differing ages and with different underlying diseases were frequently assessed as a single group [Callahan et al, 1994]. An ideal cohort should be a clearly defined sample representative of patients receiving joint arthroplasties so that valid inferences may be deducted. The lack of admission criteria reported in articles was exemplified in a critique of orthopaedic literature (1972 to 1987) by Gartland (1988) who found five of ten articles reported no criteria for admission. This, in part, may be related to inconsistent terminology of disease classification and severity. In spite of the American Orthopaedic Association's attempts to standardize definitions, a definitive classification of arthritis is still debated within the literature [Altman, 1991; Peyron, 1986].

Another methodological limitation has been the type of measure used to evaluate the outcome; these measures have been based on clinical findings rather than patient-based and had poor validity, reliability and sensitivity [Liang et al, 1982]. Furthermore, physicians tend to rate patients' general health, mobility, pain and quality of life higher than patients, particularly when patients were more dissatisfied with their surgery, thus reflecting higher success rates [Lieberman et al, 1996].

Lastly, further confusion is created by poor study designs [Drake et al, 1994; Gartland, 1988]. This was exemplified by a literature search of hip arthroplasty studies by Gross (1988) who found only four prospective studies published between 1960 and 1986. Less rigorous study designs such as descriptive or patient-based retrospective cohort have commonly been used.

2.13 Summary

Population-based studies have shown marked increases in the utilization rates of total joint arthroplasties over the past two decades. These rates are expected to continue to rise as life expectancy improves, and the prevalence of arthritis increases [Quam et al, 1991; Seagroatt et al, 1991; Madhok et al, 1993; Overgaard et al, 1992]. Although comprehensive literature exists concerning surgical and technological outcomes [NIH, 1994; Callahan et al, 1994], relatively few studies have prospectively examined pain relief, functional status or health-related quality of life. To date, no studies have

prospectively evaluated these HRQoL outcomes in a community-based cohort. Nor have many studies addressed determinants of these outcomes [MacWilliam et al, 1996; Sharma et al, 1996; Braeken et al, 1997]. Most studies have been conducted as a part of clinical trials evaluating the outcomes of specific prostheses in highly selected patients, as opposed to population-based inception cohorts undergoing usual care. Notwithstanding the general clinical acceptance of hip and knee arthroplasties, there is limited evidence using patient-based outcomes such as overall health status. Furthermore, no studies have compared pain, function and HRQoL outcomes in the elderly patients to the typical age group that receives joint arthroplasty. Consequently, indications and contraindications for joint arthroplasties are vague and reflect the ambivalence of patient appropriateness.

The primary aim of this study is to evaluate the pain and functional outcome after total joint arthroplasties in a community-based cohort. Previous studies have included small case series, and have not adequately examined quality of life for this patient group nor identified determinants of pain or function. The evaluation of health-related quality of life in this context is crucial. Disease-specific outcomes are important to determine improvement in particular areas (e.g. pain or disability). The elderly population has increasing comorbidity and disability; therefore, the efficacy of costly interventions also has to be measured in relation to the patients' overall health status. Quality of life instruments allow us to determine if improvement in a specific domain (e.g. pain and disability in a single joint) has an overall impact in health-related quality of life. In view of the gains attained with this surgery, further information regarding patient characteristics predictive of pain and function would provide patients and surgeons with a realistic estimation of their outcomes.

2.14 Significance

Most studies that have examined pain and functional outcomes after joint arthroplasties have been based on small case series, as opposed to population-based cohorts. Poorly defined indications and contraindications for joint arthroplasties are reflected in variation of practice patterns and utilization rates [Katz et al, 1996]. A concern of health administrators is that expensive, elective surgical procedures may be inappropriately overutilized. In an era of healthcare accountability, healthcare professionals are being asked to demonstrate that interventions they provide are beneficial. As the population ages, increasing demands will also be placed on caregivers by patients who expect the best possible care irrespective of their age. Physicians will be faced with opposing views and requests, and will need information to provide equitable and effective care. This study will provide useful information to assist in surgical rationalization of total joint arthroplasty and identification of patients who may require further support after surgery.

Table 2-1. Summary of studies that examined joint arthroplasty in older patients.

tudy	Study design	Population	N	Age (yrs)	Outcome	Follow-up	Results
rander 1997)	prospective 1 surgeon at 1 hospital 1988-1993	THA/ TKA = primary/ revisions	46 TKA 43 THA 10 bilat TKA 89 control 71% OA	83 (80-93) 71 (65-79)	medical chart: HHS; HSS;FIM	25 (3-67) mon	- TKA LOS 11.5 (6-27) days; THA 10.9 (4-24); LOS similar for age groups - younger group healthier = 45% had no comorbidities; 80+ group 33% had no comorbidities - HSS pre-post measures had comparable improvement for both groups - HHS pre- post measures had comparable improvement for both groups - no difference with complication rates
evy 1995)	retrospective hospital chart review	THA	76 randomly selected charts 86% OA	85 (80-97)	Charnley modified D'Aubigne-Postel	59.4 (26-146) mon	- LOS 19 (12-39) days - no fatalities within 6 months after surgery - 6% post-operative mental confusion; 4% hip dislocation -98% very satisfied - 96% maintained same level of independence; 94% lived in community
osick 1994)	retrospective 1 surgeon at 1 hospital 1981-1991	TKA (cemented)	107	83 (80-92)	chart review: included KSRS	within 2 yrs	- 14% had no comorbidities - 7% cases had surgical complications - post-operative confusion most noted post-op problem (34%) - 2 peri-operative deaths - 31% transferred for further rehabilitation; 10% discharged to nursing homes - 'excellent' pain relief & 'modest' functional gains
dam 1994)	retrospective 1 surgeon at 1 hospital 1981-1989	TKA- total condylar	34 = 65% OA 28% RA 56 control = 40% OA	79 (75-85) 62 (47-74)	BOAKA via interview	5.5 (2-10.5) yrs	- LOS = 22 days for 75+ group / 16 days for control group - older group = more pre-op medical disease 3% vs. 0 % control group - no difference with post-op complication; - 83% had good or excellent results vs. 90% control group
icat 1993)	prospective 1 hospital 1984-1988	TKA	45 (50 knees) 45 (50) control	83 (80-95) 68 (65-69)	HSS; x-ray	6 wks, 3 mon, 6 mon, 1yr, 2yr, 3 yr	- 1 peri-operative death in the older group - no difference with pain, function, ROM, strength, stability, los, costs - HSS= 98% complete pain relief older group and 81% of younger group; - 6% older and 12% younger group had complications
acobsson 1991)	prospective 1986-1988	THA	37 = 36 = control 34 THA-OA 6 hip fracture	82.0 (sd 2.3) 64.8 (sd 9)	chart review, HHS-interview	26 (sd 7) mon	- LOS (31.1 days) was longer than control group (13.6 days) - 3 peri-operative deaths in older group - 18 complications for the older group, vs. 2 in control group - HHS- 64.4% scored 'good to excellent' - increased qol for the older group = pain relief, 'modest' function gains

ewington 1990)	retrospective 1 hospital 1978-1985	THA-primary	107 (112 hip) 94% OA	83.8 (80+)	chart review: HHS	3 yr. (3 mon-8 yr.)	- LOS = 37 days - 4 peri-operative deaths - 20 DVT, 9 acute confusion, 7 urinary retention 17 hip dislocations - HHS = 76% satisfactory results
etersen 1989)	not stated 1978-1982	THA	27= 1 bilateral; 18 unilateral 8 revisions	82 (80-88)	HHS Charnley modified D'Aubigne-Postel social function	31 (13-64) mon	- LOS 30 (9-90) days; 10 dc rehab x 60 days; no deaths; - complication = 2 infections, 3 dislocation, 1 peroneal n. palsy; - 12/22 had 'good to excellent' HHS , - no social gains as measured by Thomas & Stevens
hillips 1987)	retrospective 1 hospital 1978-1986	THA elective primary/ revision	91	82.8	chart review:	2 yrs	- LOS 20 days; 70 discharged home directly - 2 peri-operative deaths - 33 had no complications = 8 major 18 moderate 88 minor in 27 patients
oettcher 1992)	retrospective 2 hospitals 1980-1986	THA 22 OA; 18 hip fracture	42	83 (80-96)	chart review:	5 yr.	- LOS= 16 days - 1 peri-operative death; - 75% had complications (excessive bleeding, post-op confusion, urinary retention).

Abbreviations

OA	osteoarthritis
THA	total hip arthroplasty
TKA	total knee arthroplasty
TJA	total joint arthroplasty
LOS	length of stay
BOAKA	British Orthopaedic Association Knee Assessment
FIM	Functional Independence Measure
HHS	Harris Hip Score
HSS	Hospital for Special Surgery
KSRS	Knee Society Rating Score

Table 2-2 Summary of total joint arthroplasty studies that have recognized comorbid conditions.

Study	Cohort	Measurement of comorbid conditions	Findings
MacWilliam et al, 1996	THA (n=442)	◆ number and type ◆ Charlson Comorbidity Index was originally used	◆43% had 1 or more comorbid conditions ◆each additional comorbid condition is reflected in a 4.6 and 4.7% decrease in pain and function scores. ◆ presence of chronic back pain/sciatica reflected a 9.6% decrease in the change of pain scores. ◆ presence of visual impairment reflected a 15% decrease in change of function
Greenfield et al, 1993	THA (n=356)	Index of Co-Existent Disease (ICED)	◆ patients with moderate comorbidity scores (ICED level 3) had 3 times the likelihood of developing minor complications after surgery. ◆ ICED was a significant predictor of 1 year functional status (ADL, IADL, social activity questions)
Kantz et al, 1992	TKA (n=109)	number and type	◆ the presence of comorbid condition was reflected in lower pain and function scores. ◆ the average number of comorbid conditions was 3 ◆ back problem was the most prevalent comorbid condition. ◆ back problem had a significant negative impact on the score of the SF-36 (physical function and bodily pain subscales)
Bayley et al, 1995	THA (n=90) TKA (n= 117)	presence/absence	◆ the presence/absence of comorbid conditions was found not to be a statistically significant factor in pain or functional scores.
Munin et al, 1995	TJA (n=162)	number and type	◆ comorbid conditions was used for descriptive purposes; ◆ 48% (78) had 2 or more comorbid conditions. ◆ coronary artery disease was the leading medical comorbid condition; 20% (32) ; diabetes was the second leading condition; 12% (19).
Ritter et al, 1995	THA (n=85) TKA (n=93) bilateral TKA (n=65)	number	◆ those patients with 'significant' comorbid conditions were excluded from the study. ◆ mean number of conditions were reported for THA (0.870), TKA (1.12), and bilateral TKA (1.23).

Abbreviations
THA Total hip arthroplasty
TKA Total knee arthroplasty
TJA Total joint arthroplasty

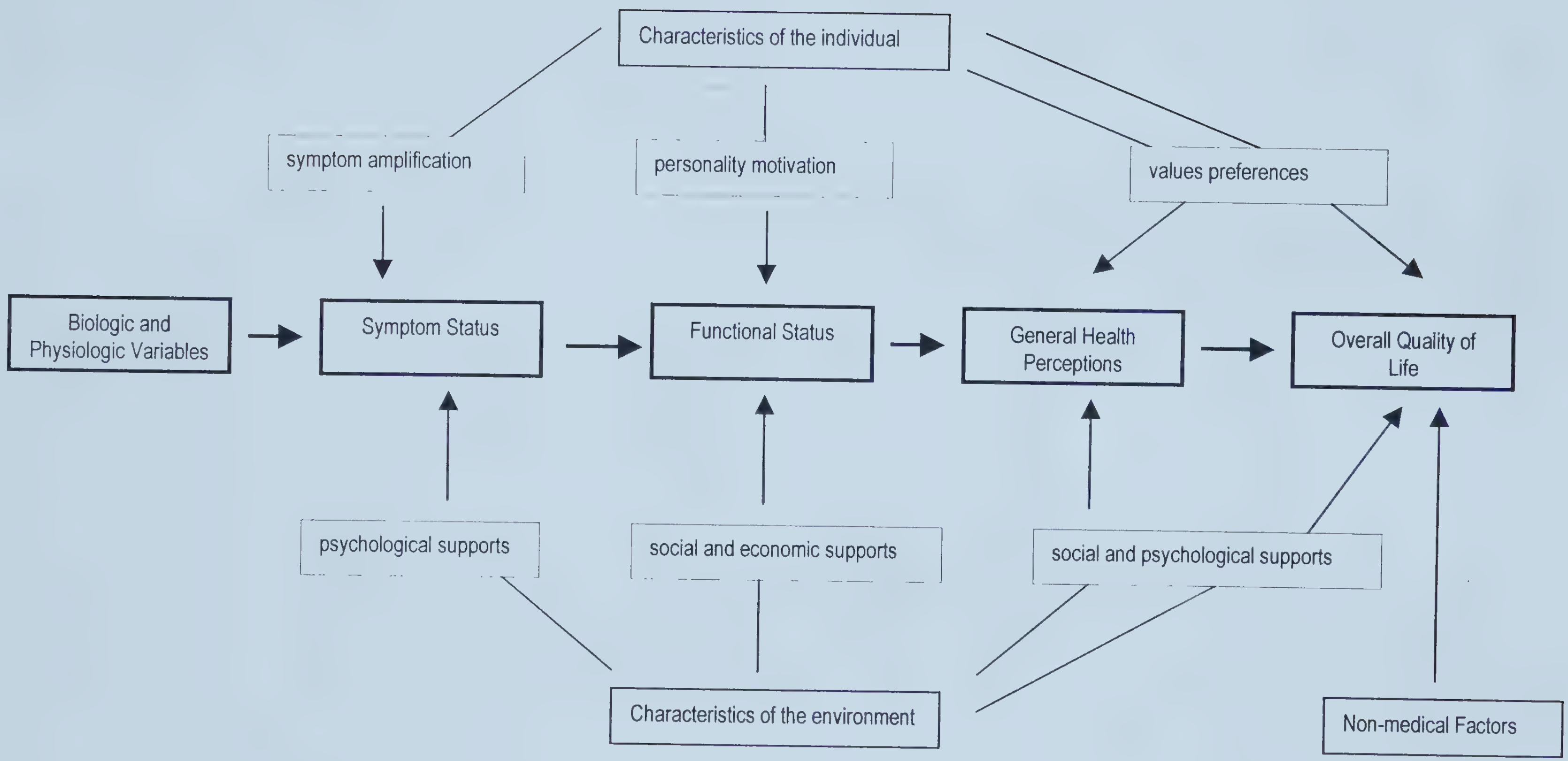
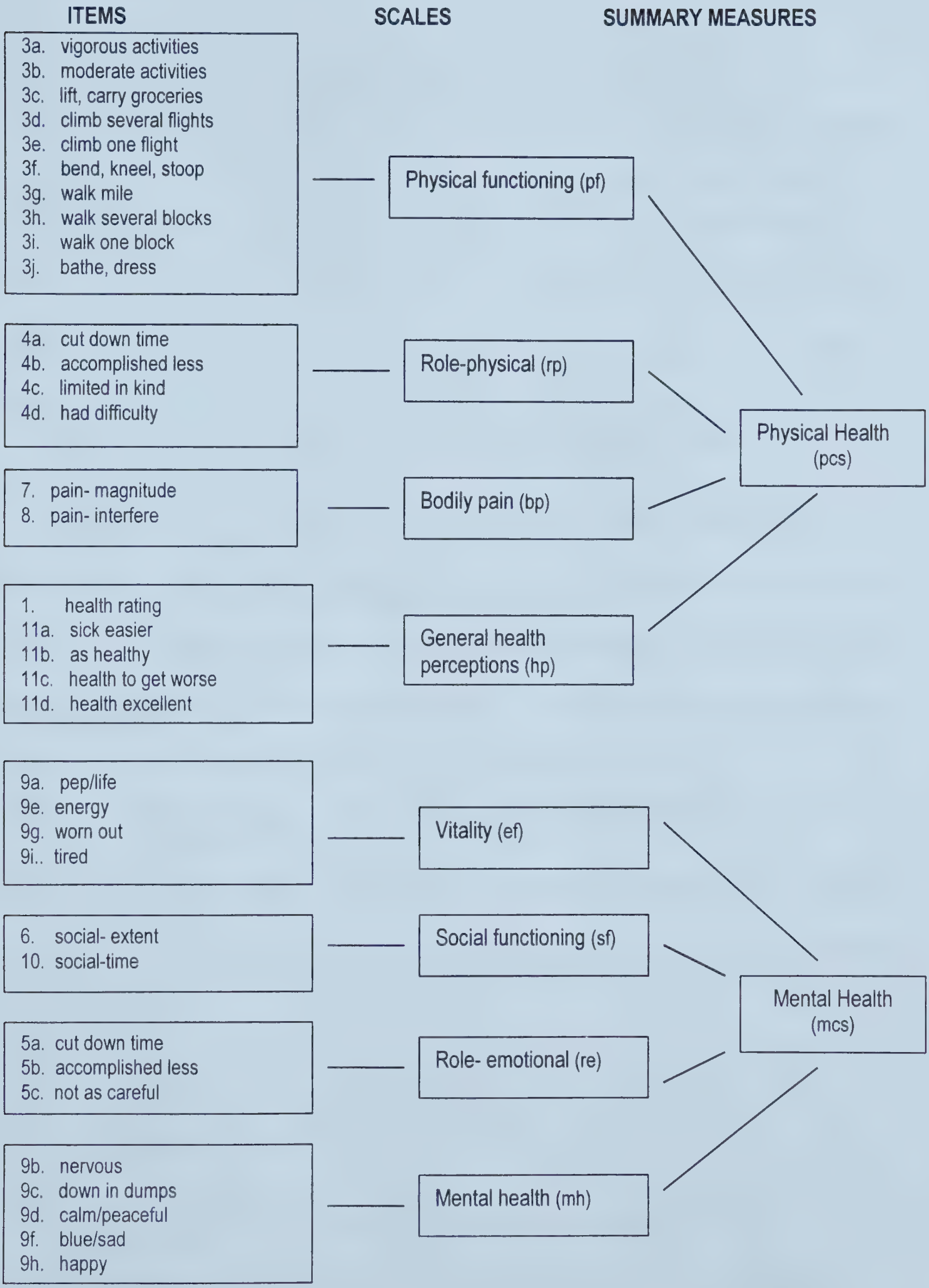


Figure 2-1. Health-related quality of life conceptual model proposed by Wilson & Cleary, 1995

Figure 2-2: SF-36 Measures (Adapted from Ware et al, 1994)



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CHAPTER 3

Health-related quality of life after total hip and knee arthroplasties in a community-based population.

3.0 INTRODUCTION

Total hip and knee arthroplasties (THA/TKA) are widely accepted orthopaedic surgical procedures used to relieve pain and improve function. Because of an aging population, high prevalence of arthritis among the elderly, and technological prosthetic advancements, the demand for total joint arthroplasties has been steadily increasing [Coyte et al, 1997; Williams et al, 1994; Madhok et al, 1993].

Extensive clinical evidence supports high surgical success of joint arthroplasties; however, outcomes have been typically expressed in terms of technical ratings, clinical impairments, health services utilization, post-operative complications, mortality, and revisions [Coyte et al, 1997; Callahan et al, 1994; Drake et al, 1994; Gartland, 1988; Lavernia & Guzman, 1995; Baron et al, 1996; Whittle et al, 1993; Holmberg, 1992; Seagroatt et al, 1991]. While these outcomes are not directly reflective of pain relief and function, more recent studies have used patient questionnaires to evaluate pain, function, and health-related quality of life (HRQoL) [Hawker et al, 1998; Laupacis et al, 1993, Bayley et al, 1995; Rissanen et al, 1996; Ritter et al, 1995]. Further studies have also advocated the use of both disease-specific and generic health measures to evaluate outcomes of joint arthroplasties [Kantz et al, 1992; Bombardier et al, 1995].

Findings concur that the greatest improvement of pain and function occurs within the first three to six months after surgery [Laupacis et al, 1993; MacWilliam et al, 1996; Rissanen et al, 1997; Aarons et al, 1996]. Evidence from clinical studies report a higher proportion of patients with pain relief than functional improvements [Laupacis et al, 1993; Rissanen et al, 1996; MacWilliam et al, 1996; Rissanen et al, 1995]. The amount of improvement reported after surgery is not clearly defined [Callahan et al, 1994], yet a higher proportion of patients with THA report improvement than patients with TKA [Ritter et al, 1995; Rissanen et al, 1995; Kirwan et al, 1994].

Not only are improvements seen with pain and function, but health-related quality of life such as social function, mental health and vitality also improve after surgery. A review of the literature identified eleven studies which examined HRQoL in patients undergoing joint arthroplasties (see section 2.7). These studies have typically been conducted as a part of clinical trials evaluating the outcomes of specific prostheses in highly selected patients or evaluated from administrative databases [Laupacis et al, 1993; McGuigan et al, 1995; Rissanen et al, 1996] as opposed to population-based inception cohorts undergoing usual care. Furthermore, six of these studies examined patients within a year of surgery [van Essen et al, 1998; MacWilliam et al, 1996; Ritter et al, 1995; Bayley et al, 1995; Laupacis et al, 1993; Wiklund &

Romanus, 1991], while the follow-up of the other studies ranged from two to twenty years [McGuigan et al, 1995; Rissanen et al, 1996; Hilding et al, 1997; Franzen et al, 1997; Hawker et al, 1998]. The greatest amount of change appears to occur within two years after surgery [Bayley et al, 1995; Ritter et al, 1995; Rissanen et al, 1995]. It is unclear whether the gains seen with HRQoL dimensions are joint dependent [Rissanen et al, 1996; Ritter et al, 1995; Liang et al, 1986].

While published findings have reported successful outcomes, patient selection is usually restricted to either one surgeon or a tertiary centre. Some authors have suggested that surgeons with more experience have better patient outcomes than less experienced surgeons [Lavernia & Guzman, 1995], which may limit the generalizability of the results from single centres to the arthritic population at large. A community-based cohort is one type of study group that may be more representative of the total patient population and reflective of general practice patterns. Only one study has evaluated this type of cohort. Hawker and colleagues (1998) conducted a cross-sectional survey of a random sample of 1193 Medicare recipients who had undergone TKA. They reported improvements in pain and function two to seven years after surgery. Although patients were representative of the TKA population, the authors acknowledged the shortcomings of a retrospective patient-based survey such as recall bias. No studies, to date, have prospectively examined pain, function and HRQoL outcomes after total joint arthroplasties in an inception community-based cohort.

The primary purpose of this study was to quantify the magnitude of change seen with pain, function and quality of life 6 months after THA and TKA in a community-based cohort. The secondary objective was to compare the magnitude of change seen with THA to TKA.

3.1 METHODS

3.1.1 Patient selection

A community-based inception cohort of patients recommended for either primary THA or TKA was assembled within a Canadian health region (Edmonton, AB). The cohort had been gathered for another study examining waiting list times and subsequently, selection criteria were related to the time of placement on the list rather than the time of surgery. The selection criteria included patients who were a) scheduled for elective total hip or knee arthroplasty, b) placed on the health region's waiting list during December 18, 1995 and January 24, 1997, c) placed on the waiting list for at least seven days before their surgery, d) residing within the health region, e) 40 years or older, and f) English-speaking. Patients undergoing hemiarthroplasties, revisions and emergency arthroplasties were excluded, as well as those patients residing in long-term care institutions.

Among the 709 patients placed on the waiting list, 84 (12%) had their surgeries cancelled either for medical reasons or personal choice. A remaining total of 625 patients were identified within the health region based on the selection criteria. Of the selected patient group, 84 (13%) patients refused or could not be contacted to request participation. Another 7 patients had their surgery prior to being contacted and 30 (5%) patients were lost to follow-up. This corresponds to a participation rate of 81%. The final study cohort was comprised of 504 patients, 228 and 276 who received THA and TKA, respectively.

There were 26 orthopaedic surgeons who performed joint arthroplasties at either of the two hospitals within the health region. An equal proportion of surgeries was performed at each hospital. Standardized pre and post-operative care was ensured by a standardized care map of medical, rehabilitation, and community services used within the health region.

3.1.2 Study protocol

Once patients' names appeared on the regional joint replacement waiting list, they were contacted to request participation in the study. Upon agreement, in-person interviews were arranged. Patients were informed that they could withdraw from the study at any time without affecting their medical care. Written consent was obtained from all participants.

The pre-operative interview was completed within 31 days prior to surgery by one of three trained health care professionals who were not involved in patient care of the participants. This assessment included a disease-specific questionnaire, *Western Ontario and McMaster Universities* (WOMAC) *Osteoarthritis Index* [(a) Bellamy et al, 1988; (b)Bellamy et al, 1988], a generic health status questionnaire, *SF-36 Health Survey* (SF-36) [Ware & Sherbourne, 1992; McHorney et al, 1994; Stewart et al, 1988], comorbidities, demographic characteristics, and social support. A second interview was conducted 6 months after the surgery which included the WOMAC and SF-36 questionnaire, as well as three questions concerning patient satisfaction.

Data regarding surgical procedures, diagnosis, peri-operative care, in-hospital complications, and discharge destination were extracted from medical charts. Significant in-hospital complications such as wound infection, pulmonary emboli, deep venous thrombosis, dislocation, urinary tract infection, acute confusion, neurological and vascular problems as diagnosed by the physician were recorded. Information regarding subsequent hospital readmissions within 6 months of discharge, community rehabilitation within two months of surgery, and home care services was gathered from regional databases.

3.1.3 Measures

Joint-specific pain, function and stiffness were measured using the WOMAC [(a) Bellamy et al, 1988; (b)Bellamy et al, 1988]. The self-administered questionnaire consists of three subscales: pain (5 items), stiffness (2 items), and physical function (17 items). Responses were based on a five point Likert scale. Aggregate scores were calculated for each dimension since no global score can be calculated for the WOMAC. The reliability and validity of the WOMAC have been evaluated in this patient population [Bombardier et al, 1995; (a) Bellamy et al, 1998].

Health-related quality of life was assessed using a generic health questionnaire, the SF-36 [Ware & Sherbourne, 1992]. This questionnaire assesses eight health subscales: bodily pain, physical function, physical role function, mental health emotional role function, vitality, social function, and general health perceptions, and also provides two summary measures: physical component summary (PCS) and the mental component summary (MCS). Reliability and validity have been extensively evaluated in a variety of patient populations including total hip and knee arthroplasties [Kantz et al, 1992; Bombardier et al, 1995; McHorney et al, 1994; Brazier et al, 1992; Lyons et al1994; Stucki et al, 1995]. Results are presented for each dimension and the two component summary measures as there is no global score for the SF-36. Four age groups and gender normative values from the general U.S. population (ten year intervals ranging from 35 to 65+ years) were also used for each of the eight dimensions and summary scores [Ware & Sherbourne, 1992; Ware et al, 1994].

Patient satisfaction was measured by three questions regarding overall satisfaction, pain relief and functional recovery: "*How satisfied are you with your joint replacement surgery?*", "*How successful was your joint replacement surgery in relieving your pain?*", and "*How successful was your joint replacement surgery in allowing you to return to your normal activities?*". A five point Likert scale was used for the responses, with higher scores representing greater displeasure.

3.1.4 Statistical analyses

Each WOMAC subscale score was transformed to a range of 0 (worst) to 100 (best), similar to the SF-36 subscales. This type of transformation has been used by others to facilitate comparison of these two scales [Bombardier et al, 1995]. Improvement for the WOMAC was defined as a gain of at least 60% of the baseline standard deviation. This proportion represented a gain of at ten points from the pre-operative score; whereas, deterioration was considered a loss of ten or more points.

Effect sizes were also calculated for the WOMAC and SF-36. This method standardizes scores dividing the difference between the pre-operative and 6 month follow-up scores by the standard deviation of pre-operative score from the group. Because there is no accepted definition of clinically meaningful change

for health status, standardization is one means of comparing change between questionnaires and controlling for sample variation [Kazis et al, 1989; Deyo & Patrick, 1995]. An effect size of 1.0 indicates a change of 1 baseline standard deviation. Effect sizes were calculated rather than using the SF-36 criterion referencing since it is a simple method to express a standardized measure of change for different questionnaires. The descriptive analysis of our data showed variation in the spread of the different subscales, which also supported the use of effect sizes to compare across measures. Furthermore, there are no criterion references for the WOMAC.

The pre-operative and 6 month mean values of the SF-36 were compared to the age:sex adjusted norm-based values (35-44; 45-54; 55-64; 65 and above). The 6 month mean for each dimension and component summary score based on age group and gender was compared to the norm-based value for the value. An overall age:sex adjusted norm value for each dimension and component summary score was also calculated based on the age and gender distribution of the joint groups. The mean differences were compared for overall norm value and joint group's value for each dimension and summary score. Norm values for the SF-36 were only used since the WOMAC does not have norm-based values.

Data were analyzed with respect to joint replaced. Chi square tests and nonparametric analysis of variance (ANOVA) were used to identify differences between categorical variables, and *t*-tests and ANOVA were used to identify mean differences of continuous variables that were normally distributed. Nonparticipants were compared to participants to identify any systematic differences between the two groups. A similar comparison was completed to compare losses to follow-up to the final study population. All statistical testings were 2-tailed at a 0.05 level of significance. Statistical analyses were performed using the SPSS software version 7.5.

3.2 RESULTS

3.2.1 Patient Characteristics

Nonparticipants (121) were similar to the study group (504) with respect to age; 67.6 $\pm$ 10.1 years as compared to 68.5 $\pm$ 10.1 years ($p=0.37$). No differences existed for the proportion of females in the nonparticipant (55%) and study groups (59%) ($p=0.41$). This was also true for the type of joint replaced; 41% of nonparticipants received THA while 45% of the study group had THA ($p=0.44$). Of those patients lost to follow-up (30), no differences were seen when compared to the study cohort with respect to age, joint, gender, diagnosis, number of comorbid conditions, pre-operative health perception, previous joint replaced, and living arrangements ($p>0.05$).

Baseline characteristics: The mean age of patients with THA was 68.2± 11.1 years and 69.2± 9.2 years for patients with TKA. There were 299 women and 471 (93%) patients had a diagnosis of osteoarthritis.

The average number of comorbid conditions was similar for both joint groups, 3.5 (range 0 to 13). Hypertension (HBP) and lower back pain (LBP) were the two most commonly reported conditions. Patients with THA were more likely to report LBP (37%) than patients with TKA (25%) ($p=0.003$). Furthermore, 46% (104) of patients had bilateral hip involvement and 58% (158) bilateral knee involvement. The THA group had a higher proportion of patients with previous joints replaced (33%) than the TKA group (24%) ($p=0.046$). The TKA group had a significantly higher body mass index (BMI= kg/m^2), 31.6 ± 5.9 than the THA group, 29.3 ± 5.6 ($p<0.001$).

Surgical characteristics: The mean length of stay was similar for both groups, 7.0 ± 3.6 days. All patients underwent unilateral joint arthroplasties; however, 28 patients had the contralateral joint (9 hips and 19 knees) replaced 6 months before or after the evaluated joint. Approximately 60% of the prostheses were hybrid, 134 THA and 157 TKA; that is, one prosthetic component was cemented. A further 36% (82) THA and 15% (42) TKA were cementless.

The incidence of in-hospital complications was similar for THA and TKA groups, 0.34 per patient. The most frequently cited complications were urinary tract infection (32), and then thrombi/emboli (22). Only one hip revision was performed within 6 months of surgery; however, 12 patients were seen in emergency after discharge for prosthetic related reasons. There were three deaths; two due to pulmonary embolism within one month of surgery and the other due to a non-related cause.

Rehabilitation: Approximately 58% (286) patients were discharged directly home while approximately 40% (202) were transferred to other institutions for rehabilitation. Among those patients who were discharged home, 90 (69%) patients with THA and 165 (62%) with TKA received home care and/or outpatient physical therapy services.

3.2.2 Outcomes

Joint-specific pain, function and stiffness (WOMAC). Overall, the majority of patients reported improvement in pain, function and stiffness at 6 months from their pre-operative scores ($p< 0.001$), irrespective of the joint replaced. Both joint groups had similar pre-operative WOMAC scores for pain ($p= 0.77$) and stiffness ($p= 0.71$). Those patients with hip involvement reported greater dysfunction than patients with knee involvement prior to surgery ($p= 0.004$). Although both joint groups had similar pre-operative pain and stiffness scores, the THA group had greater pain relief, functional improvement and less stiffness at 6 months than the TKA group ($p< 0.05$) (Fig. 3- 1; Appendix D).

As shown in Figure 3-2, a higher proportion of patients with THA reported an increase of at least 10 points from their pre-operative scores than patients with TKA ($p < 0.001$). Ninety-two percent (208) of THA group reported pain relief as compared to 81% (222) of the TKA group. A similar trend was also seen with function and stiffness; 87% (198) of the THA group reported improvement with function as compared to 78% (214) of TKA group. Among the THA group, 86% (196) reported improvement in stiffness, whereas, only 75% (206) of the TKA patients were better.

Generic health status (SF-36): Pre- and post-operative scores were significantly different ($p < 0.05$) for all dimensions and component summaries of THA and TKA. The change in score ranged from 7 to 36% for THA and 6 to 24% for TKA. See Appendix D for means and standard deviations.

At baseline the health subscale was the only subscale within norm values for the THA and TKA groups ($p > 0.05$). At 6 months the following subscales were within the norm values:

a) THA: health, social function, mental health, vitality, MCS

b) TKA: health, mental health, MCS

At 6 months the following subscales were below the norm values:

a) THA: bodily pain, physical function, role physical, role emotion, PCS

b) TKA: bodily pain, physical function, role physical, social function, role emotion, vitality, PCS

Although large improvements were reported in the 6 months scores for physical function and role function, these subscales did not reach the values reported in the general population for age and gender (Appendix D: age:sex adjusted groups). Additionally, patients with TKA did not attain bodily pain scores at 6 months similar to these adjusted norm values. The 6 month bodily pain reported by the THA group showed a trend towards the norm values. Alternately, those subscales with fewer changes such as health and mental health were within norm values. While these similarities were reflected in mental summary scores comparable to the general population for age and gender, the physical summary scores were lower than the general population.

Effect sizes: A high proportion of patients reported improvement in both joint groups, yet the magnitude of change seen was dependent upon the joint as seen in Table 3-1. Larger changes were seen in THA group for pain, function, and stiffness than TKA group for pain, function, and stiffness ($p<0.05$) (Appendix D).

Although the effect sizes for the SF-36 were not as great as the values reported with the WOMAC, larger changes were seen with bodily pain, function, and the physical component summary score than with the other subscales. Modest changes were seen in the general health perceptions and vitality subscales.

Patient satisfaction: Similar trends were also seen with patient satisfaction. The overall satisfaction rate for the THA group was 92% (203) as compared to the TKA group, 77% (204) (Fig. 3-4). Satisfaction was reflected in the amount of improvement reported regardless of joint. Among the THA group, 6 (3%) felt the success of the surgery was minimal in relieving their pain. This was in contrast to 34 (13%) of the TKA group who felt that surgery did not relieve their pain. Twenty-six (12%) of the THA group and 49 (19%) of the TKA group felt that surgery had little, if any success on resuming their regular functional activities. Mean differences of joint-specific pain and function were seen among the levels of satisfaction. Patients who reported large improvements with were more satisfied with their surgery. Significant differences among the means were found with effect size and the overall satisfaction with the surgery ($p < 0.001$).

3.3 DISCUSSION

Findings from this community-based cohort concurred with clinical studies that THA and TKA are effective means of relieving pain and improving function. The largest gains were seen with joint specific pain and function (WOMAC) while larger gains were seen with bodily pain physical function, physical limitations and the PCS of the SF-36. Moderate changes were seen with social function, vitality, mental health, emotional limitations, health perceptions and the MCS of the SF-36. The effect sizes reported were considered large for most HRQoL dimensions [Kazis et al, 1989], in excess of one standard deviation from the baseline scores; however, moderate changes were seen with psychosocial variables such as role emotional, mental health, and general health perceptions.

Although larger changes were seen with function, the SF-36 physical function scores at 6 months were less than the US population norms. This was also true for bodily pain scores although the THA group was near those values of the general population. These findings suggest that joint arthroplasties improve pain and function to a level that is not comparable to the general population. Furthermore, while smaller changes were reported with mental health, general health perceptions and vitality, the 6 month scores were comparable to the general population.

Contrary to other studies which have reported similar changes with THA and TKA [Ritter et al, 1995; Liang et al, 1986], the magnitude of change reported in this study was joint-dependent. Those patients with THA reported greater improvements than patients with TKA in with joint-specific pain and function, as well as most HRQoL areas. Moreover, these differences seen would suggest that THA and TKA cohorts should be evaluated and analyzed as two separate study groups. This observation has previously been recommended by others [Gartland, 1988], but not quantified.

A review of the literature found eleven articles that evaluated HRQoL and all reported 'good' to 'excellent' results in pain, function and overall health (see section 2.7). In spite of the favourable results,

criticism has been directed toward the study methodology [Callahan et al, 1994; Gartland, 1988; Drake et al, 1994]. Most study designs have limited generalizability because of retrospective design or limited patient representation[Gartland, 1988; Rissanen et al, 1996]. While one other study has evaluated HRQoL outcomes in a community-based cohort, this study was a cross- sectional survey of Medicare beneficiaries [Hawker et al, 1998]. Further, the authors recognized the potential limitations of their study such as recall bias.

This study cohort is likely representative of a community-based population for three reasons. Firstly, patients were first identified when they were placed on the waiting list by their orthopaedic surgeons and prospectively followed. Secondly, other patient study cohorts have frequently been restricted to either a surgeon or hospital [Laupacis et al, 1993; Bayley et al, 1995; Sharma et al, 1996]. Subsequently, the generalizability is limited because higher volume surgeons tend to have better outcomes than surgeons with lower volumes [Lavernia & Guzman, 1995]. This study cohort included patients from the community who were treated within a universal health region by 26 orthopaedic surgeons with low to high surgical volumes. Furthermore, treatment of patients within the acute-care, rehabilitation, and community settings was standardized with the use of patient caremaps for both THA and TKA. Lastly, this patient cohort was restricted to elective primary surgeries.

The overall satisfaction rate which was high for both THA (92%) and TKA (77%), was comparable to other satisfaction rates [Mancuso et al, 1997; Dickstein et al, 1998]. The improvement of pain and function are closely related to patient satisfaction, yet other HRQoL measures are also related to satisfaction [Bayley et al, 1995; Ritter et al, 1995; Mancuso et al, 1997]. Although outcome and satisfaction appear to be related, a myriad of other factors affect patients' satisfaction which in turn, will have implications for determining those suitable candidates for surgery.

3.4 CONCLUSIONS

Findings from this community-based cohort showed large improvements in pain and function after total hip and knee arthroplasties. These large changes also had an impact on the quality of life of these patients. Moderate changes were also seen with psychosocial factors; these changes were dependent upon the type of joint replaced. Although large gains were seen with pain and function, these improvements were not to a level comparable with the general population when adjusted for age and gender. Those areas that showed smaller changes were already within the norm values and would not be expected to dramatically change.

Overall, greater gains were reported with THA than TKA. Because the changes differed with the type of joint replaced, patients with THA and TKA should be evaluated as two separate study groups. The

majority of patients reported improvements in pain and function after joint replacements and are satisfied with their surgery; however, a certain proportion of patients do not improve. Further studies are needed to identify clinical factors that can predict pain and functional improvement after surgery.

Table 3-1: Effect sizes* for joint groups with the WOMAC and SF-36 scores.

	THA (*n* = 228)	TKA (*n* = 276)
WOMAC	mean ± standard deviation	
pain	2.6 ± 1.3	1.9 ± 1.2
function	2.5 ± 1.4	1.6 ± 1.2
stiffness	1.7 ±1.3	1.1 ± 1.2
SF-36		
bodily pain	2.4 ± 1.8	1.3 ± 1.4
physical function	1.7 ± 1.6	1.3 ± 1.4
role physical	1.7 ± 2.1	1.0 ± 1.7
general health	0.3 ± 1.0	0.1 ± 1.0
social function	1.0 ± 1.1	0.7 ± 1.0
vitality	0.9 ± 1.1	0.5 ± 1.0
mental health	0.5 ± 1.0	0.3 ± 1.0
role emotional	0.5 ± 1.2	0.3 ± 1.2
physical component	2.0 ± 1.7	1.2 ± 1.3
mental component	0.4 ± 0.9	0.2 ± 1.0

$$\text{* Effect size} = \frac{\text{pre-operative individual score} - \text{6 month individual score}}{\text{standard deviation of pre-operative joint group score}}$$

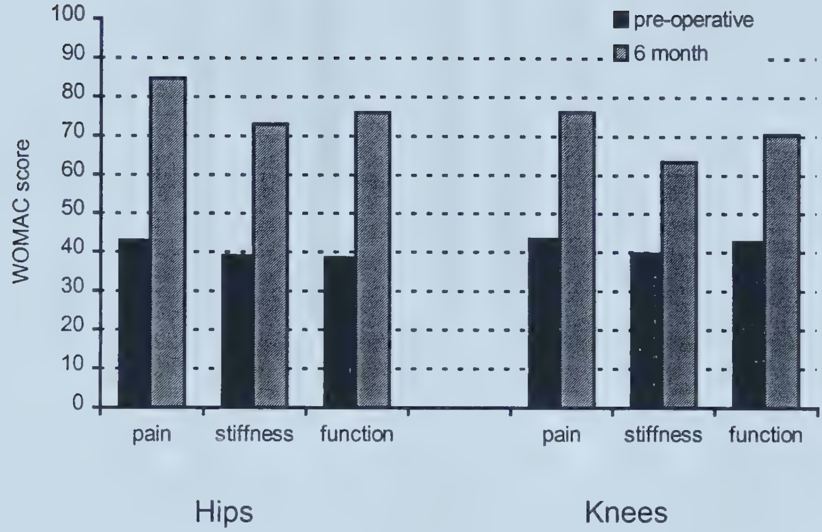

Figure 3-1: Mean WOMAC scores for the pre-operative and 6 month follow-up of the THA (*n*=227) and TKA (*n* =276) groups. Scores range from 0 (worst) to 100 (best). All three subscales showed significant improvement for all pre- and post-operative measures ($p < 0.001$). The change in scores for THA ranged from 34 to 42%; whereas TKA change in scores ranged from 24 to 33% for pain, stiffness and function. See Appendix D for values.

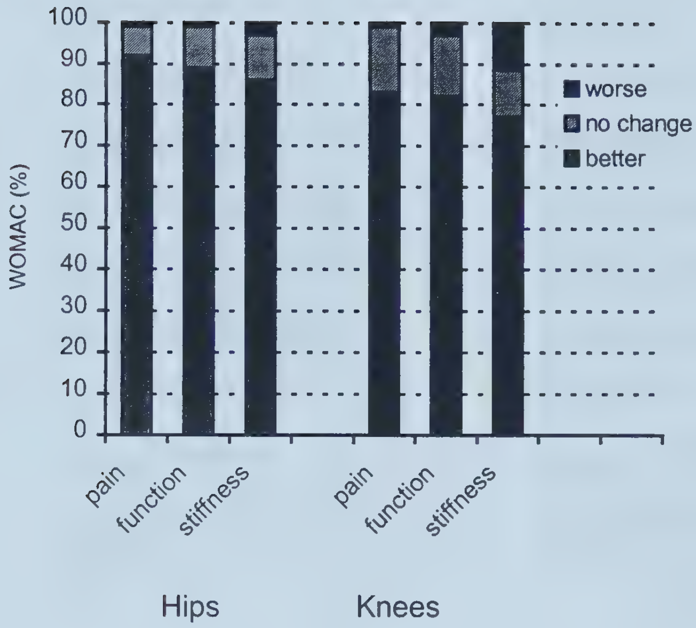

Figure 3-2: Percentage of patients who showed improvement of WOMAC scores as compared to patients who did not change or deteriorated. Patients with TKA (n = 276) did not show as great as improvement as those patients with THA (n = 227). An improvement was a gain of at least ten points; whereas, deterioration was considered a loss of ten points from the pre-operative score.

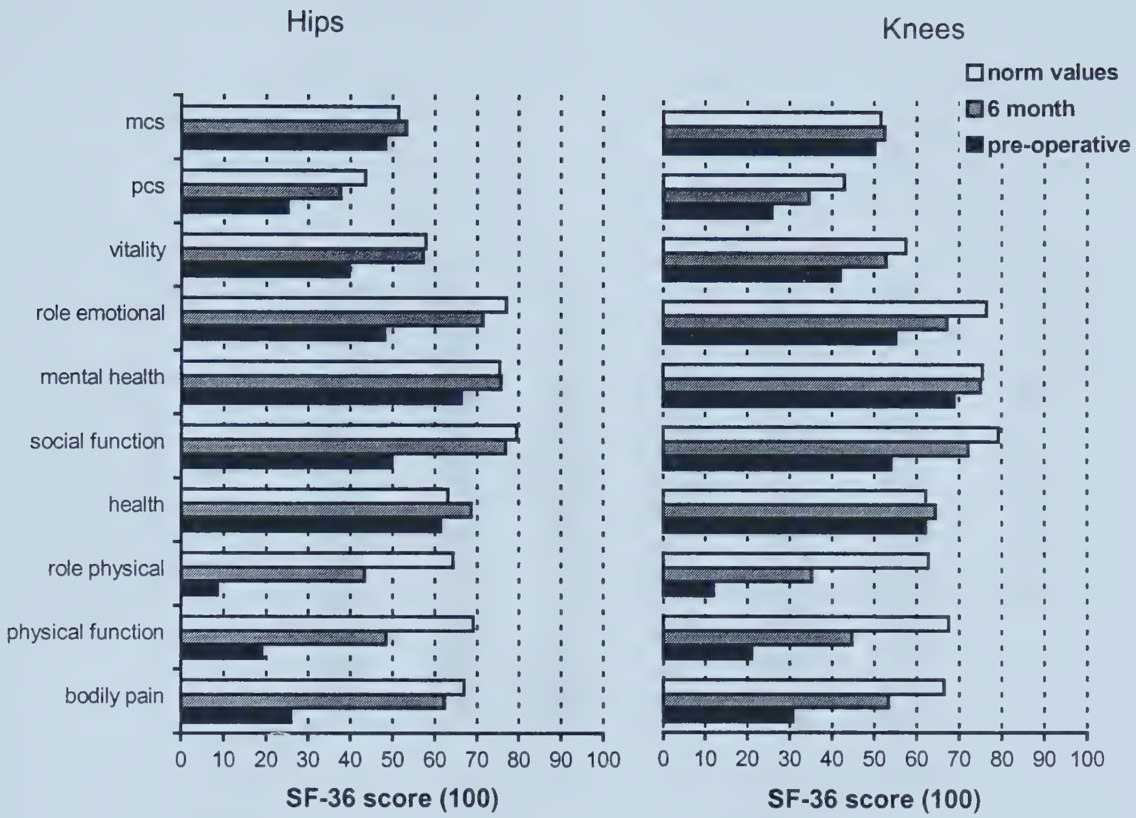

Figure 3-3: Mean health-related quality of life (SF-36) scores for the eight dimensions and two component summary scores (PCS and MCS) of the pre-operative and 6 month assessments for the THA (*n* = 228) and TKA (*n* =276) groups. A score of 100 represents no difficulties, whereas, 0 represents the worst problems for each of the eight dimensions. Scores less than 50 for the component summaries indicate scores below the average value of the general U.S. population.

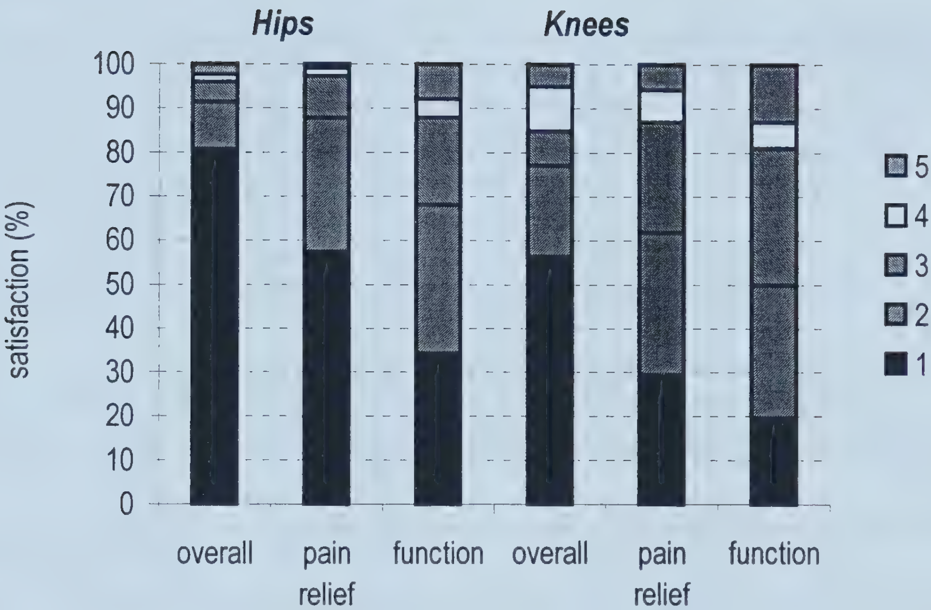

Figure 3-4. Patient satisfaction. Overall satisfaction, pain relief, and function were rated on a 5 point Likert scale with higher scores representing dissatisfaction. Overall satisfaction was greater for patients with THA (n = 222) than TKA (n = 266). A similar trend was seen for satisfaction with pain relief and functional improvement.

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CHAPTER 4

The effect of age on pain and functional outcomes after total hip and knee arthroplasties.

4.0 INTRODUCTION

Utilization rates for both total hip and knee arthroplasties (THA/ TKA) have been steadily increasing in spite of the ambiguity regarding determinants for this surgery [Katz et al, 1996; Wright et al, 1995]. Although joint arthroplasties are effective surgical treatment for arthritis of the hip and knee, geographic variation exists, and this may be related to clinical uncertainty of patient appropriateness for this surgery.

Outcomes measuring pain, function, and health-related quality of life after total joint arthroplasties have frequently been examined in heterogeneous patient groups. A major criticism expressed by some is that many study cohorts include patients of varying ages [Gartland, 1988; Callahan et al, 1995]. These studies, nevertheless, report favourable findings. Overall, more than 75% of patients report pain relief and improved function [MacWilliam et al, 1996; Bayley et al, 1995].

The effect of age on pain, function, and HRQoL outcomes after THA and TKA is not clearly understood. Total hip and knee arthroplasties are typically performed on patients between 60 and 75 years [Quam et al, 1991; Madhok et al, 1993; NIH, 1995; Callahan et al, 1994]. In spite of an aging population and prosthetic advancements, the average age for joint replacements has not increased [Katz et al, 1996; Madhok et al, 1993]. In a cohort study of Medicare beneficiaries, Katz and colleagues (1996) reported that receiving a TKA was a function of age. Those patients 85 years or older were less likely to receive TKA than their younger counterparts. Hesitancy to perform this surgery in older patient populations may not be related to age itself, but rather associated with comorbid conditions and post-operative complications.

While favourable pain and functional outcomes of joint arthroplasties in patients 80 years or older have been presented in descriptive studies, concerns regarding higher complication and mortality rates have been expressed [Adam & Noble ,1994; Newington et al, 1990; Phillips et al, 1987; Petersen et al, 1989; Hosick et al, 1994]. The generalizability of these findings, however, is restricted because of the descriptive or retrospective study designs used. Findings from more rigorous study designs, case controlled studies (matched for gender, diagnosis and surgery) concurred that older patients (80 to 95 years) receiving joint arthroplasties attained similar pain and functional levels as the younger group (65 to 79 years) over two year follow-up) [Brander et al, 1997; Zicat et al, 1993]. In contrast to previous descriptive studies, these

studies did not report higher complication rates in the older group. In light of the limited evidence, much clinical controversy exists with respect to age and the risk of surgery when considering joint replacements. Subsequently, surgeons are confronted with weighing the risks and benefits of joint arthroplasties for older patients.

While the benefits and risks of joint arthroplasty have primarily been described in small clinical study groups of highly selected patients, no study has prospectively compared these outcomes in a community-based study group of patients 80 years or older to a younger patient group. This is the first prospective community-based study comparing pain, function, and HRQoL outcomes after total joint arthroplasties in patients 80 years or older to a younger group. Because utilization rates continue to increase and secondary factors affecting surgery are unclear, the effect of age needs to be evaluated in this patient population. The primary purpose of this study was to prospectively compare pain, functional and HRQoL outcomes after THA and TKA in an older patient group, 80 years or older, to a cohort who represented the typical age of patients receiving joint arthroplasties (55 to 79 years).

4.1 METHODS

4.1.1 *Patients*

A prospective community-based cohort study of patients recommended for either primary THA or TKA was conducted within a Canadian health region (Edmonton, AB). This was an inception cohort which had been assembled for another study examining waiting list times. Subsequently, selection criteria were related to the time of placement on the waiting list rather than the time of surgery. The study design has been reported in detail in an earlier study [Jones et al, 1999]. Selection criteria for this present study identified patients who were a) scheduled for primary total hip or knee arthroplasty, b) placed on the regional joint replacement waiting list for at least 7 days before their surgery, c) resided within the health region, d) 55 years or older, and e) English-speaking. Surgical procedures excluded from this study were hemiarthroplasties, revisions and emergency arthroplasties. Participants who resided in long-term care institutions were also excluded.

Based on the selection criteria, a total of 558 patients were identified within the health region between December 18, 1995 and January 24, 1997. Among this patient group, 71 (13%) refused or could not be contacted to request participation. Another 7 (1%) patients had their surgery prior to being contacted and 26 (5%) patients were lost to follow-up. This corresponded to a participation rate of 81%. The final study cohort consisted of 454 patients, 197 and 257 who received THA and TKA, respectively. Three deaths occurred within the TKA group during follow-up. Two died within one month of discharge from

pulmonary emboli and were in the younger age group (55 to 79 years). The third death, which was from the older group, was unrelated to surgery. Among the participants who received THA, 163 (83%) were between 55 and 79 years of age, 34 (17%) were 80 years or older. Two hundred and twenty-two (86%) participants who underwent TKA, were between 55 and 79 years, 35 (14%) were 80 years or older.

Participants received their surgeries between January 1996 and February 1998. Indications for arthroplasties were pain, function, and/or deformity which did not respond to conservative management. No bilateral joint surgeries were performed during this study period. All 26 orthopaedic surgeons who were practicing at either one of the two hospitals within the health region participated in the study. An equal proportion of surgeries was performed at each hospital. Treatment was ensured by standardized caremaps for THA and TKA within the acute care, homecare, and community rehabilitation settings.

4.1.2 *Study protocol*

When patients' names appeared on the regional joint replacement waiting list, they were contacted to request participation in the study. Upon agreement, in-person interviews were arranged. Patients were informed they could withdraw from the study at any time without affecting their medical care. Pre-operative interviews were completed within 31 days prior to surgery and follow-up interviews were performed 6 months after surgery. Assessments were completed by one of three health professionals (two nurses and a physical therapist) who were not involved in patient care of the participants. During these interviews, information regarding pain, function, HRQoL, socio-demographic, and medical status were gathered.

4.1.3 *Measures*

Joint-specific pain and functional outcomes were evaluated with a self-administered health questionnaire, *Western Ontario and McMaster Universities* (WOMAC) *Osteoarthritis Index* [(a)Bellamy et al, 1988; (b)Bellamy et al, 1988] (Appendix A). The WOMAC is designed to measure disability of the osteoarthritic hip and knee [(a)Bellamy, 1988; Hawker et al, 1995]. Each item is scaled using a five point Likert scale and aggregate scores for joint-specific pain (5 items), physical function (17 items), and stiffness (2 items) are calculated. While the use of an overall score is not recommended, each subscale score was transformed to a range from 0 to 100 points, with a score of 100 indicating no pain, dysfunction or stiffness [Bombardier et al, 1995]. It is a responsive, reliable and valid instrument and has been extensively used to evaluate this patient population [(a)Bellamy et al, 1988]. The WOMAC is more sensitive to change following joint arthroplasty than the dimensions of physical function and bodily pain from the SF-36 [Bombardier et al, 1995].

Health-related quality of life domains were measured using a generic health status questionnaire, *SF-36 Health Survey* (SF-36) [Ware & Sherbourne, 1992; McHorney et al, 1994; Stewart et al, 1988]. This generic health measure is a self-administered 36 item questionnaire compromised of eight health dimensions: bodily pain, physical function, role limitations related to physical health (physical role function), mental health, role limitations related to emotional health (emotional role function), social functioning, vitality, and general health, as well as two summary measures: physical component summary (PCS) and the mental component summary (MCS) (Appendix A). There is no global score for the SF-36. Scoring for each scale range from 0 to 100 points, with higher scores representing better health. This scoring contrasts the scores used in both summary measures which are norm-based to the general U.S. population and have a mean of 50 and a standard deviation of 10 [Ware et al, 1994]. Normative values from the general U.S. population for two age groups (55 to 65 years and 65 years or older) and gender are also used for each of the eight dimensions and summary scores [Ware & Sherbourne, 1992; Ware et al, 1994]. Because 65 years or older age group is the oldest age group for the SF-36 normative data, the 80 or older age group was compared to the normative data from a relatively younger group.

Reliability and validity have been extensively evaluated in a variety of patient populations including total hip and knee arthroplasties and elderly persons both residing in the community and undergoing elective surgery [Kantz et al, 1992; Bombardier et al, 1995; McHorney et al, 1994; Brazier et al, 1992; Lyons et al, 1994, Stucki et al, 1995; Mangione et al, 1993]. Furthermore, the SF-36 is responsive to change in patients with joint arthroplasties [Bombardier et al, 1995].

Socio-demographic and medical information including age, gender, education, previous joint arthroplasty, and living arrangements were collected at the baseline interview. The number of self-reported chronic conditions were collected using a list of 23 items [Charlson et al, 1987] and presented as a simple additive score [MacWilliam et al, 1996]. Data regarding the type of implant fixation (cemented, hybrid or cementless), the number and type of in-hospital complications (wound infection, dislocation, manipulation under anaesthesia, cardio-respiratory, peripheral/central nervous system involvement, urinary infection, acute confusion, blood loss requiring transfusion after surgery), and other medical information such as diagnosis were extracted from medical charts by two health professionals. Health services utilization data were extracted from the regional database.

4.1.4 *Statistical analyses*

Effect sizes were calculated for the WOMAC and SF-36. This method standardizes age group scores dividing the difference between the pre-operative and 6 month follow-up scores by the standard deviation of pre-operative score. Because there is no accepted definition of meaningful clinical change for

health status, standardization is one means of comparing change between questionnaires and controlling for sample variation [Kazis et al, 1989; Deyo & Patrick, 1995]. An effect size of 1.0 indicates a change of one baseline standard deviation.

Because pain and functional outcomes are different for THA and TKA [Ritter et al, 1995; Rissanen et al, 1995], the data were analyzed with respect to the type of joint replaced. Statistical analyses were performed using the SPSS software version 7.5. All statistical testing was performed with two-tailed tests and at a 0.05 level of significance.

Frequency distributions, means and standard deviations were calculated for all continuous variables. If the variables were not normally distributed, medians and quartiles were calculated. Chi square tests and nonparametric analysis of variance (ANOVA) were used to identify differences between categorical variables, and Student's *t*-tests and ANOVA's were used to identify differences between continuous variables that were normally distributed. Differences between the baseline and 6 month values were identified for joint specific (WOMAC) and generic HRQoL measures (SF-36) using paired *t*-tests. Mean values for the pre-operative and 6 months values of the SF-36 were compared to the age:sex adjusted norm-based values of the SF-36.

Multiple linear regression analyses were used to evaluate the effect of age on pain and function while controlling for possible confounding effects of other variables. Separate models were fit for each of the two outcomes, pain and function, for both joint groups. The difference between the baseline and 6 months scores for pain and function as measured by the WOMAC were the two dependent variables. Independent variables were selected based on their clinical significance or bivariate association with the dependent variables. The independent variables for analysis of pain included age, gender, pre-operative bodily pain (SF-36), the number of comorbid conditions, implant fixation, length of stay in the acute care hospital, and waiting time for surgery. Independent variables forced entered for analyses of function consisted of age, gender, pre-operative joint pain (WOMAC), physical function (SF-36), body mass index (BMI= kg/m^2), the number of comorbid conditions, living arrangements, contralateral joint involvement, length of stay in the acute care hospital, and waiting time. Age in all regression analyses was treated as a continuous variable.

4.2 RESULTS

4.2.1 *Patient Characteristics*

No differences were seen between the final study cohort and those patients who did not participate. Nonparticipants (104) were similar to the study group (454) with respect to age; 70.8 ± 6.6 years as compared to 70.7 ± 8.0 years (p=0.91), respectively. No differences existed with respect to gender (p=0.78), type of joint replaced (p=0.46) or hospital site (p= 0.73).

Among the patients who received THA, the mean age for the younger group was 68.8 ± 3.5 years (*n*= 163) and 83.6 ± 2.6 years for the older group (*n*= 34). The mean age for the younger group who received TKA was 68.8 ± 6.4 years (*n*= 222) and 82.9 ± 2.0 years for the older group (*n*= 35). Demographic and baseline data are summarized in Table 5-1. The majority of patients were older women who were diagnosed with osteoarthritis. There were no age group differences for diagnosis, gender, or education; however, older participants were more likely to live alone (p< 0.001) . Younger patients who received THA were heavier (BMI= 29.7 ± 5.2) than their older counterparts (BMI= 26.8 ± 4.3); however, no weight differences were seen with the two TKA groups (p> 0.05).

<u>Comorbid conditions</u> The vast majority of patients had at least one comorbid condition. All patients among the older patient groups for THA and TKA had at least one comorbidity. Eight patients from the younger groups with THA (5%) and TKA (4%) reported no comorbid conditions. As seen in Table 4-1, the mean number of comorbid conditions was similar for both age groups regardless of joint replaced (p> 0.05). The most frequently cited problem for patients with hip involvement was lower back pain regardless of age: 39% (63) of the younger group and 44% (15) of the older group. Hypertension was the most common condition of the TKA group (40%), regardless of age group. Interestingly, eye problem was the second most cited condition among the older groups for THA (38%) and TKA (31%).

<u>Health services utilization</u> As shown in Table 4-2, the average waiting time for surgery ranged from 74 to 108 days; however, there was no statistical difference with respect to age group. The mean acute hospitalization for patients who received THA was similar regardless of age group (p= 0.64); however, the younger group with TKA had a slightly longer length of stay (LOS), 6.9 ± 1.8 days, than the older group, 6.1 ± 2.1 days (p= 0.04). Although the acute care LOS was similar, a greater proportion of the older patients was transferred to rehabilitation facilities; 70% (23) of the THA group and 82% (28) of the TKA group. Only 40% of the younger group were transferred. The LOS at the rehabilitation facilities was similar for both age groups (p> 0.05) (Table 4-2).

Surgical factors The majority of THA and TKA were hybrid, that is, only one prosthetic component was fixated with cement (Table 4-2). Younger patients who received THA were more likely to receive cementless prostheses (34%) than older patients (3%); however, this was not the situation with the TKA group. No age differences were seen with the type of implant fixation provided for TKA.

While the majority of patients had no in-hospital complications, the incidence of in-hospital complications was 0.39 complications per patient for the younger groups regardless of joint. Among the older patient THA and TKA groups, these rates were 0.55 and 0.41, respectively. These values did not represent statistical differences ($p > 0.05$). As seen in Table 4-2, urinary tract infection and deep venous thrombi were the most frequently cited complications among the younger group [also see Appendix F]. Urinary tract infection was the most frequently reported complication for patients 80 years or older.

4.2.2 *WOMAC outcomes*

Total hip arthroplasties Patients regardless of age showed significant improvement in pain, function and stiffness (Fig. 4-1). Overall, 93% (183) patients reported pain relief, 88% (173) had functional improvement, and 86% (169) attained positive gains with stiffness. Among those patients who received THA, the mean baseline and 6 month follow-up scores were similar regardless of age group (Appendix F).

The mean baseline pain score was 42.9 ± 16.0 for patients under 80 years and 42.5 ± 17.5 for those 80 years or older ($p = 0.91$). The 6 month pain scores improved at 6 months to 84.0 ± 17.0 for the younger group and 88.5 ± 19.3 for the older group ($p = 0.17$). Although the vast majority reported functional improvement, the gains were lower than the pain scores. The mean baseline function score for the younger group was 38.8 ± 15.1 and 35.7 ± 15.2 for those patients 80 years or older ($p = 0.24$). The 6 month scores improved to 76.4 ± 17.1 and 76.7 ± 23.4 for the younger and older groups, respectively ($p = 0.80$). Stiffness showed a similar trend. The mean baseline score for the younger group was 38.7 ± 19.8 and improved at 6 months to 70.9 ± 20.0. For the older group, the baseline stiffness score was 40.8 ± 22.5 and increased at 6 months to 80.9 ± 19.8.

Total knee arthroplasties A similar trend was also seen for patients with TKA (Fig. 4-1). Pain scores showed the greatest improvement and no differences were seen with age. Overall, 84% (217) experienced pain relief, 81% (202) had functional improvement, and 77% (194) reported less stiffness.

The mean baseline pain score for the younger group was 43.6 ± 17.9 and improved at 6 months to 77.6 ± 18.8; whereas the mean baseline score was 41.2 ± 16.1 and at 6 months was 72.9 ± 19.8 for the older group. No age group differences were seen between baseline pain scores ($p = 0.67$) or 6 month scores ($p = 0.17$). Like the THA group, functional gains were less than the improvement seen with pain.

The mean baseline function score for the younger group was 43.4 ± 17.7 and 38.2 ± 12.0 for the older group ($p = 0.24$). At 6 months, the younger group's function improved to 72.1 ± 18.3 and 66.2 ± 16.7 for the older group ($p = 0.09$). Stiffness was similar for both groups; the baseline score for the younger group was 39.3 ± 21.2 and 43.4 ± 21.1 for the older group ($p = 0.27$). These scores improved to 63.9 ± 21.9 for the younger group and 65.1 ± 23.2 for the older group ($p = 0.78$) (Appendix F).

4.2.3 *Health related quality of life (SF-36).*

Overall, improvements were reported in most of the HRQoL areas ($p < 0.001$) regardless of age group (Fig. 4-2, Fig. 4-3, Appendix F). No statistical improvements were seen in some HRQoL dimensions such as role emotion. In general, pre-operative scores were similar for both age groups.

Total hip arthroplasties The greatest improvements were reported in bodily pain and physical function regardless of age group (Fig. 4-2). The mean change in bodily pain for the younger group was 35.6 ± 27.1 and 40.0 ± 28.9 for the older group. Large changes were also seen for physical function and role function 29.8 ± 29.0 and 35.7 ± 44.3 for the younger group. A similar pattern was seen for the older group for physical function, 26.1 ± 27.3 and role function, 30.9 ± 37.5. Smaller changes were seen with health and mental health for both age groups, but 6 month scores were within the norm values for both groups.

When compared to the norm-based values of the SF-36, the following baseline subscales were within norm values:

a) < 80 yrs = health

b) 80+ yrs = health, role emotion, MCS

At 6months the following subscales were within norm values of the SF-36:

a) < 80 yrs = bodily pain, health, social function, mental health, role emotion, vitality, MCS

b) 80+ yrs = bodily pain, health, mental health, role emotion, vitality, MCS

Those subscales that were below the norm values at 6 months were:

a) < 80 yrs = physical function, role physical, PCS

b) 80+ yrs = physical function, role function, social function, PCS

See Appendix F for values. Although bodily pain improved to the levels of the norm values, physical function at 6 months was below the norm values for both age groups.

Total knee arthroplasties Similar trends were also seen in the TKA group (Fig. 4-3); larger changes were reported for bodily pain for the younger (23.9 ± 23.9) and older (23.3 ± 23.2) groups. Large changes were

also reported for physical function for the younger (26.1 $\pm$ 24.1) and older (18.6 $\pm$ 30.3) groups. Smaller changes were seen with health and mental health, but were similar to the norm values.

At baseline the following subscales were within norm values of the SF-36:

a) < 80 yrs = health

b) 80+ yrs = health, mental health, MCS

At 6months the following subscales were within norm values of the SF-36:

a) < 80 yrs = health, mental health, role emotion

b) 80+ yrs = health, mental health, vitality, MCS

Those subscales at 6 months that were below the norm values were as follows:

a) <80 yrs = bodily pain, physical function, role function, social function, vitality, PCS

b) 80+ yrs = bodily pain, physical function, role function, role emotion, PCS

Although bodily pain and physical function showed large improvements from the baseline scores, they did not reach the norm-based values. Further, both age groups reached norm values in similar subscales. While the older group reached norm values, this group was compared to a relatively younger norm group, 65 years and above which was the oldest age group for the norm values. See Appendix F for values.

4.2.4 Effect sizes

The effect sizes for joint specific pain, function and stiffness as measured by the WOMAC are considered large, in excess of one standard deviation from the baseline values. Changes were similar to earlier reports [Jones et al, 1999], that is, greater changes were seen with pain than function or stiffness, while changes were greater for THA than TKA. These effect sizes were similar for the younger and older groups (Table 4-3).

Effect sizes were greater for joint-specific pain and function (WOMAC) than HRQoL areas (SF-36). No age group differences were found except for role limitations related to emotions (role emotion) in the THA group. The older group had a higher pre-operative score which did not change at follow-up, whereas, the younger group did improve to a level comparable to the older group.

4.2.5 Multiple linear regression analyses

As shown in Figures 4-4 and 4-5, age did not have a strong linear relationship with either pain or function. Furthermore, when age was entered into multiple linear regression while controlling for the effect of other variables, age again was not a significant variable (Tables 4-4 & 4-5). Inasmuch as age was not significant, the variables entered into the analyses accounted for 26% (THA) and 16% (TKA) of the variance seen with pain, and 38% (THA) and 25% (TKA) of the explained variance for function. Moreover, if age was significant, it would have had a small effect on the change seen with pain and function because of the small regression coefficient. When age was entered as a dichotomous variable (55 to 79 years and 80 years or older) in the regression analyses, it was not significant.

4.3 DISCUSSION

The results of this study showed those patients 80 years or older reported significant pain relief and functional improvement, as well as, positive gains in HRQoL areas. Furthermore, these changes were similar to the ones reported in a younger cohort and were comparable to the improvements revealed in other studies with younger patient groups [Bayley et al, 1995; Sharma et al, 1996; Laupacis et al, 1993]. Patients with THA reported 38-46% improvement in pain and function while patients with TKA reported less change, 28-34% regardless of age. Whereas, improvements were reported in most of HRQoL areas, older patients did not report changes in general health and mental health; however, when compared to the population norms, these values were similar to the age and gender norm-based values (Appendix F). Although receiving a total joint arthroplasty is a function of age [Katz et al, 1996; Madhok et al, 1993], this study found that joint specific pain and functional outcomes achieved at 6 months were not age dependent.

This is the first prospective community-based study comparing pain, function, and quality of life outcomes after total joint arthroplasties in patients 80 years or older to a younger group. These findings are presumed to be representative of general practice patterns since this cohort was neither restricted to one centre or surgeon. Although this cohort was community-based, the older patient group was different from other 80 year or older study groups with respect to the number of comorbid conditions and complication/ mortality rates [Brander et al, 1997; Adam & Noble, 1994; Newington et al, 1990; Phillips et al, 1987; Petersen et al, 1989]. Unlike other studies, the older patients in this study had a similar number of comorbid conditions, and complication rates as their younger counterparts. This may be due to preferential bias; that is, frail elderly patients may not have been referred for surgery.

Others have questioned performing elective surgery in the octogenarian patient because of a susceptibility towards major complications in the early post-operative phase [Petersen et al, 1989;

Newington et al, 1990; Adam & Noble, 1994]. The findings from this study did not find a higher rate of complications in the older groups as compared to patients 55 to 79 years of age. Moreover, these results concur with other findings reported in a similar patient study group [Brander et al, 1997]. While the complication rate was comparable to the younger group, the most frequently cited complications, urinary tract infection and deep venous thrombi were not considered as major complications. Overall, the 6 months mortality rate was low in this study cohort; there were two fatal pulmonary emboli in the younger group.

In spite of having a similar number of comorbid conditions and comparable complication rates, a greater proportion of older patients was transferred to rehabilitation facilities rather than being discharged directly to home. Other studies have reported that older age, living alone and an increased number of comorbid conditions are determinants of receiving in-patient rehabilitation services before returning home [Munin et al, 1995]. In this study cohort, a greater proportion of the older patients lived alone, yet all patients resided in the community at the 6 month follow-up. Although pain and function gains were not age dependent, older patients were more likely to receive subsequent in-patient rehabilitation.

4.4 CONCLUSIONS

When compared to a patient group representative of the typical age group who receive joint arthroplasties (55 to 79 years), those patients 80 years or older attained similar pain, functional and HRQoL outcomes expected for their age. Older patients were more likely to live alone and be transferred to a rehabilitation facility; however, the number of comorbid conditions and in-hospital complication rates were comparable to the younger group. Further, all older patients were residing in the community at 6 months follow-up. For the healthy person who is 80 years or older, joint arthroplasties provide comparable pain relief and functional improvement, which is also, reflected in similar HRQoL gains to the younger patient population. With increasing life expectancy and elective surgeries improving quality of life, age alone is not a factor that affects the outcome of total joint arthroplasties and should not be a limiting factor in receiving this surgery.

Table 4-1. Frequencies of demographic and medical characteristics.

	Total hip arthroplasties (n = 197)			Total knee arthroplasties (n = 257)		
	< 80 years (n = 163)	80+ years (n = 34)	significance	< 80 years (n = 222)	80+ years (n = 35)	significance
female gender	98 (60%)	24 (71%)	0.25	127 (57%)	24 (69%)	0.20
osteoarthritis	153 (97%)	31 (94%)	0.68	206 (94%)	33 (97%)	0.43
education $\geq$ high school	100 (71%)	17 (50%)	0.22	122 (55%)	14 (40%)	0.11
previous arthroplasty	57 (35%)	12 (35%)	0.99	49 (24%)	19 (25%)	0.57
living alone	43 (26%)	20 (59%)	<0.001 *	48 (22%)	18 (51%)	< 0.001 *
	mean $\pm$ standard deviation			mean $\pm$ standard deviation		
comorbidity	3.6 $\pm$ 2.3	4.0 $\pm$ 2.2	0.26	3.5 $\pm$ 2.0	4.0 $\pm$ 2.0	0.10
body mass index (kg / m^2)	29.7 $\pm$ 5.2	26.8 $\pm$ 4.3	0.003 *	31.6 $\pm$ 5.9	31.1 $\pm$ 5.3	0.62

* statistical significance at $p < 0.05$

Table 4-2: Peri-operative characteristics.

	Total hip arthroplasties			Total knee arthroplasties		
	< 80 yrs (*n* = 163)	80+ yrs (*n* = 34)	significance	< 80 yrs (*n* = 222)	80+ yrs (*n* = 35)	significance
implant fixation:						
cementless	55 (34%)	1 (3%)	< 0.001 *	33 (15%)	6 (17%)	0.65
hybrid	101 (63%)	29 (88%)		128 (58%)	17 (50%)	
cemented	5 (3%)	3 (9%)		58 (26%)	11 (32%)	
in-hospital complications:						
none	113 (70%)	20 (61%)	0.23	147 (67%)	22 (65%)	0.94
DVT	8	1		10	0	
UTI	7	5		11	3	
wound infection	4	0		5	0	
	mean $\pm$ standard deviation		significance	mean $\pm$ standard deviation		significance
waiting times (days)	102.8 ± 85.3	73.8 ± 61.2	0.06	107.9 ± 93.1	86.2 ± 80.2	0.19
length of stay (days):						
- acute care hospital	7.4 ± 5.4	7.9 ± 4.1	0.64	6.9 ± 2.0	6.1 ± 2.1	0.04 *
- rehabilitation facility	9.2 ± 3.4	8.6 ± 2.9	0.51	9.0 ± 2.7	10.5 ± 4.5	0.15
discharge directly home	96 (60%)	10 (30%)	0.002 *	132 (60%)	6 (17%)	< 0.001 *

* statistical significance at $p < 0.05$
DVT, deep venous thrombosis
UTI, urinary tract infection

Table 4-3. A comparison of effect sizes† for age groups with WOMAC and SF-36 scores .

	Total hip arthroplasties			Total knee arthroplasties		
	< 80 yrs	80+ yrs	p value	< 80 yrs	80+ yrs	p value
	(*n* = 163)	(*n* = 34)		(*n* = 221)	(*n* = 35)	
WOMAC	mean ± standard deviation			mean ± standard deviation		
pain	2.6 ± 1.2	2.6 ± 1.3	0.86	1.9 ± 1.2	1.9 ± 1.2	0.80
function	2.5 ± 1.4	2.7 ± 1.5	0.39	1.6 ± 1.2	1.9 ± 1.2	0.22
stiffness	1.6 ± 1.2	1.8 ± 1.3	0.52	1.2 ± 1.2	1.0 ± 1.1	0.57
SF-36						
bodily pain	2.5 ± 1.9	2.4 ± 1.8	0.88	1.3 ± 1.3	1.5 ± 1.5	0.45
physical function	1.7 ± 1.6	2.0 ± 2.1	0.39	1.4 ± 1.3	1.0 ± 1.6	0.06
role physical	1.7 ± 2.1	2.3 ± 2.8	0.24	1.0 ± 1.7	0.8 ± 2.0	0.38
health	0.4 ± 1.0	0.2 ± 0.9	0.23	0.2 ± 0.9	-0.1 ± 0.9	0.05
social function	1.0 ± 1.1	0.7 ± 1.1	0.14	0.7 ± 1.0	0.4 ± 1.4	0.09
mental health	0.5 ± 0.9	0.2 ± 0.7	0.08	0.4 ± 0.8	0.2 ± 0.9	0.17
role emotion	0.6 ± 1.2	0.1 ± 1.1	0.01 *	0.4 ± 1.2	0.1 ± 1.3	0.24
vitality	1.0 ± 1.2	0.8 ± 1.0	0.40	0.6 ± 1.0	0.5 ± 1.3	0.77
physical component	1.9 ± 1.7	2.6 ± 2.3	0.05	1.3 ± 1.3	1.0 ± 1.6	0.32
mental component	0.5 ± 0.9	0.1 ± 0.8	0.04 *	0.3 ± 0.9	-0.04 ± 1.0	0.08

Probability based on *t*-test

* statistically significant ($p < 0.05$)

† Effect size = $\dfrac{\text{pre-operative score} - \text{6 month score}}{\text{standard deviation of pre-operative age group score}}$

Table 4-4. Multiple linear regression: Change in pain. **

Variables	**Total hip arthroplasty** (n=194)		R^2 : 0.26		**Total knee arthroplasty** (n= 247)		R^2 : 0.16	
	Unstandardized coefficient	*Standardized coefficient*	*CI*	*p*	*Unstandardized coefficient*	*Standardized coefficient*	*CI*	*p*
intercept	59.54		(29.61, 89.46)	<0.001 *	52.41		(26.07, 78.75)	<0.001 *
age	-0.02	-0.01	(-0.41, 0.37)	0.91	0.01	0.03	(-0.24, 0.42)	0.58
female gender	6.49	0.16	(1.10, 11.91)	0.02 *	-1.10	-0.03	(-6.30, 4.11)	0.68
waiting time	0.004	0.02	(-0.03, 0.04)	0.80	0.01	0.05	(-0.02, 0.04)	0.40
length of stay	0.40	0.10	(-0.10, 0.90)	0.12	-1.31	-0.12	(-2.64, -0.01)	0.05 *
pre-operative bodily pain (SF-36)	-0.59	-0.43	(-0.77, -0.41)	<0.001 *	-0.42	-0.35	(-0.56, -0.27)	<0.001 *
number of comorbid conditions	-1.67	-0.18	(-2.83, -0.50)	0.01 *	-0.67	-0.06	(-1.96, 0.62)	0.31
cementless prosthesis	-7.08	-0.16	(-14.15, -0.01)	0.05 *	-9.48	-0.17	(-16.20, -2.77)	0.01 *

** dependent variable = difference between pre-operative and 6 month WOMAC pain score.
independent variable age was entered as a continuous variable

* statistically significant $p< 0.05$
CI = 95% confidence interval

Table 4-5. Multiple linear regression: Change in function. **

Variables	**Total hip arthroplasty** (n=193)		R^2 : 0.38		**Total knee arthroplasty** (n= 248)		R^2 : 0.25	
	Unstandardized coefficient	*Standardized coefficient*	*CI*	*p*	*Unstandardized coefficient*	*Standardized coefficient*	*CI*	*p*
intercept	87.25		(54.99, 119.50)	<0.001 *	74.42		(44.57, 103.91)	<0.001 *
age	0.28	0.11	(-0.07, 0.63)	0.12	0.06	0.03	(-0.25, 0.38)	0.69
female gender	3.12	0.07	(-2.42, 8.67)	0.27	0.43	0.01	(-4.47, 5.34)	0.86
waiting time	-0.02	-0.07	(-0.05, 0.01)	0.28	-0.002	-0.01	(-0.03, 0.02)	0.86
length of stay	-0.20	-0.05	(-0.70, 0.30)	0.43	-1.33	-0.13	(-2.53, -0.13)	0.03 *
pre-operative joint pain (WOMAC)	-0.59	-0.44	(-0.76, -0.41)	<0.001 *	-0.43	-0.38	(-0.57, -0.28)	<0.001 *
BMI	-0.68	-0.16	(-1.20, -0.17)	0.01 *	-0.31	-0.09	(-0.71, 0.10)	0.14
contralateral joint involvement	-6.83	-0.19	(-11.00, -2.65)	0.001 *	-1.68	-0.05	(-5.27, 1.91)	0.36
lives alone	-10.01	-0.22	(-15.92,-4.10)	0.01 *	-3.04	-0.07	(-8.43, 2.34)	0.27
number of comorbid conditions	-2.06	-0.21	(-3.28, -0.84)	0.001 *	-1.56	-0.16	(-2.74, -0.37)	0.01 *
pre-operative bodily pain (SF-36)	-0.11	-0.09	(-0.28, 0.06)	0.19	-0.21	-0.19	(-0.35, -0.07)	0.003 *

** dependent variable = difference between pre-operative and 6 month WOMAC pain score.
independent variable age was entered as a continuous variable

* statistically significant $p < 0.05$
CI = 95% confidence interval
BMI, body mass index (kg/m^2)

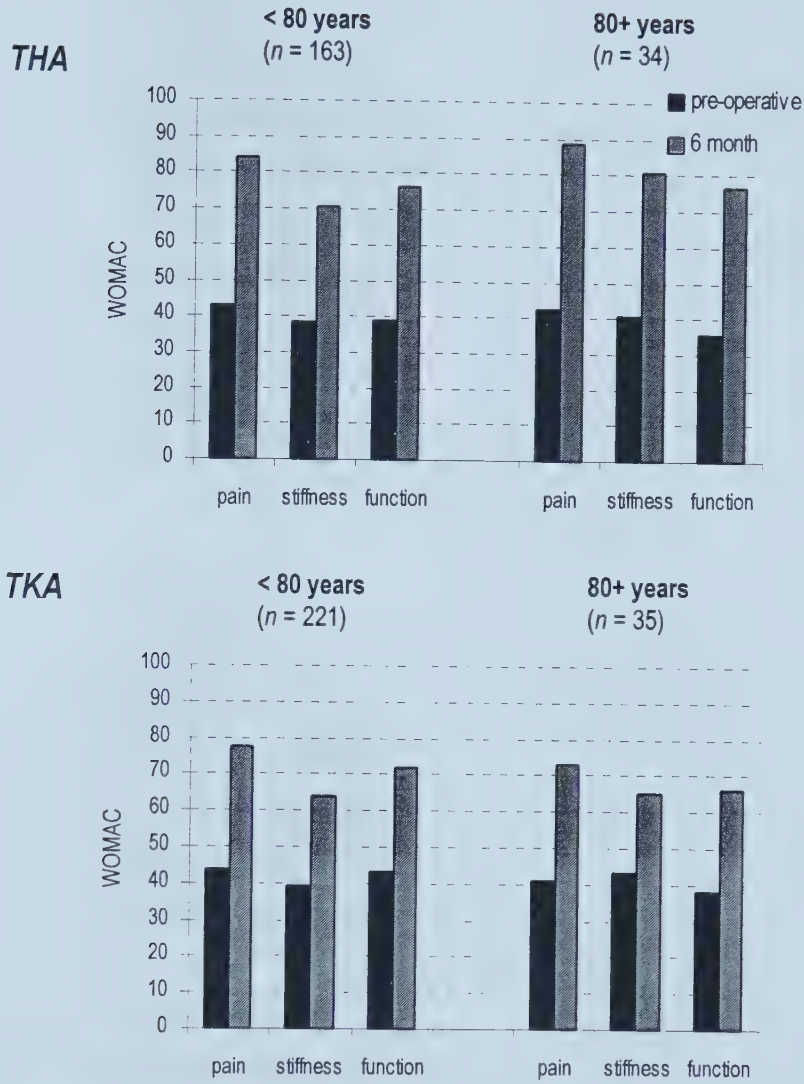


Figure 4-1: WOMAC pre-operative and 6 month scores with respect to age. All patients showed an improvement in pain, stiffness and function from their pre-operative scores ($p < 0.001$). Both age groups had similar pre-operative and 6 month scores ($p > 0.05$) except for stiffness. The younger group with THA reported greater stiffness at 6 months than the older group ($p = 0.01$). See Appendix F for means and standard deviations.

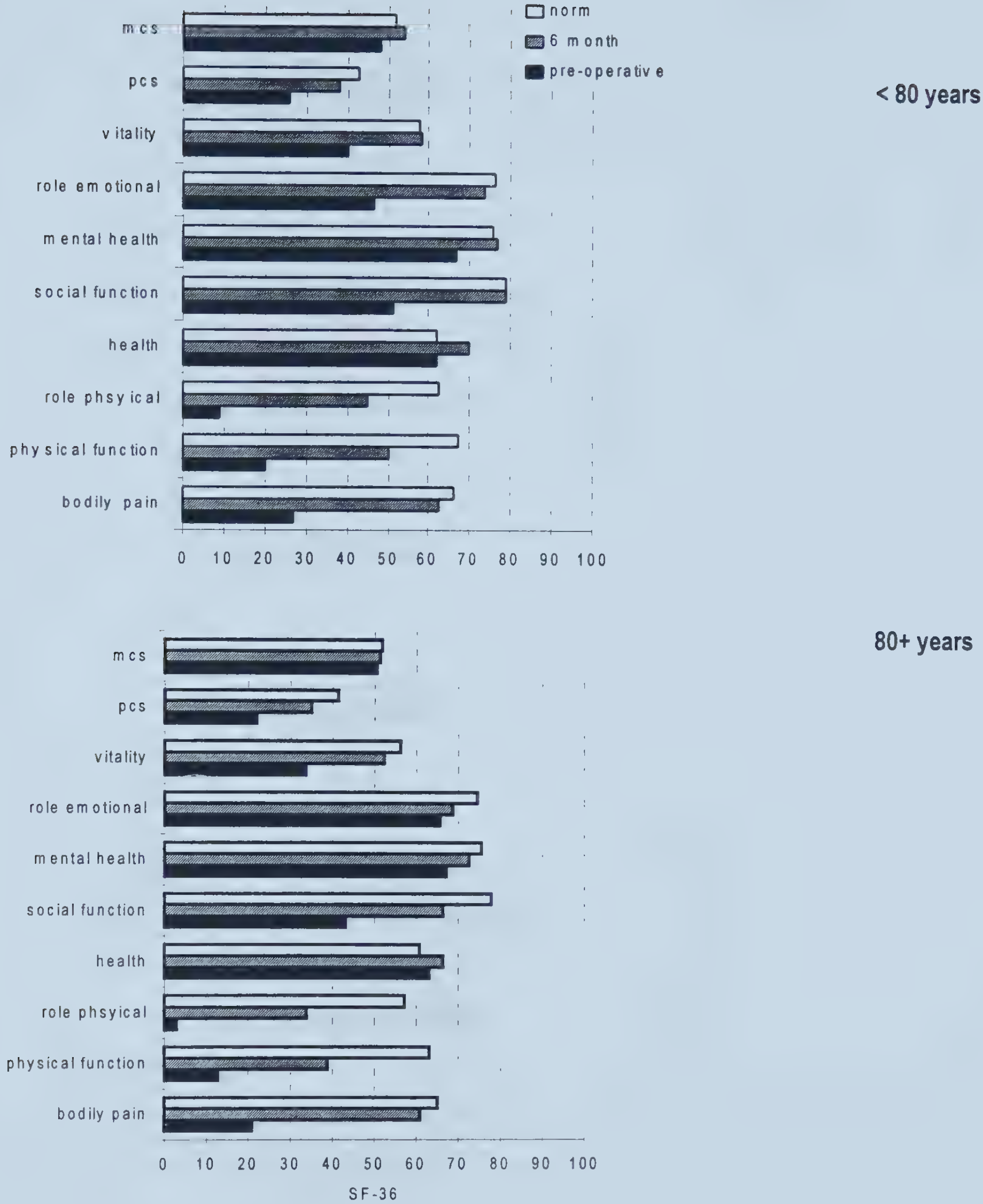


Figure 4-2: SF-36 pre-operative and 6 month scores of patients with total hip arthroplasties. Patients < 80 years old (n = 163) showed an improvement in all areas (p < 0.001) (upper graph), and patients 80+ years (n = 34) did not change with health perception (p= 0.35), mental health (p= 0.07), role emotion (p= 0.71), and mental summary score (p= 0.41) (lower graph). The older group had lower pre-operative score for bodily pain, physical function, and role physical. They did have a higher pre-operative score for role emotion. At 6 months, the 80+ group still had a lower physical function and less social function. See Appendix F for means and standard deviations

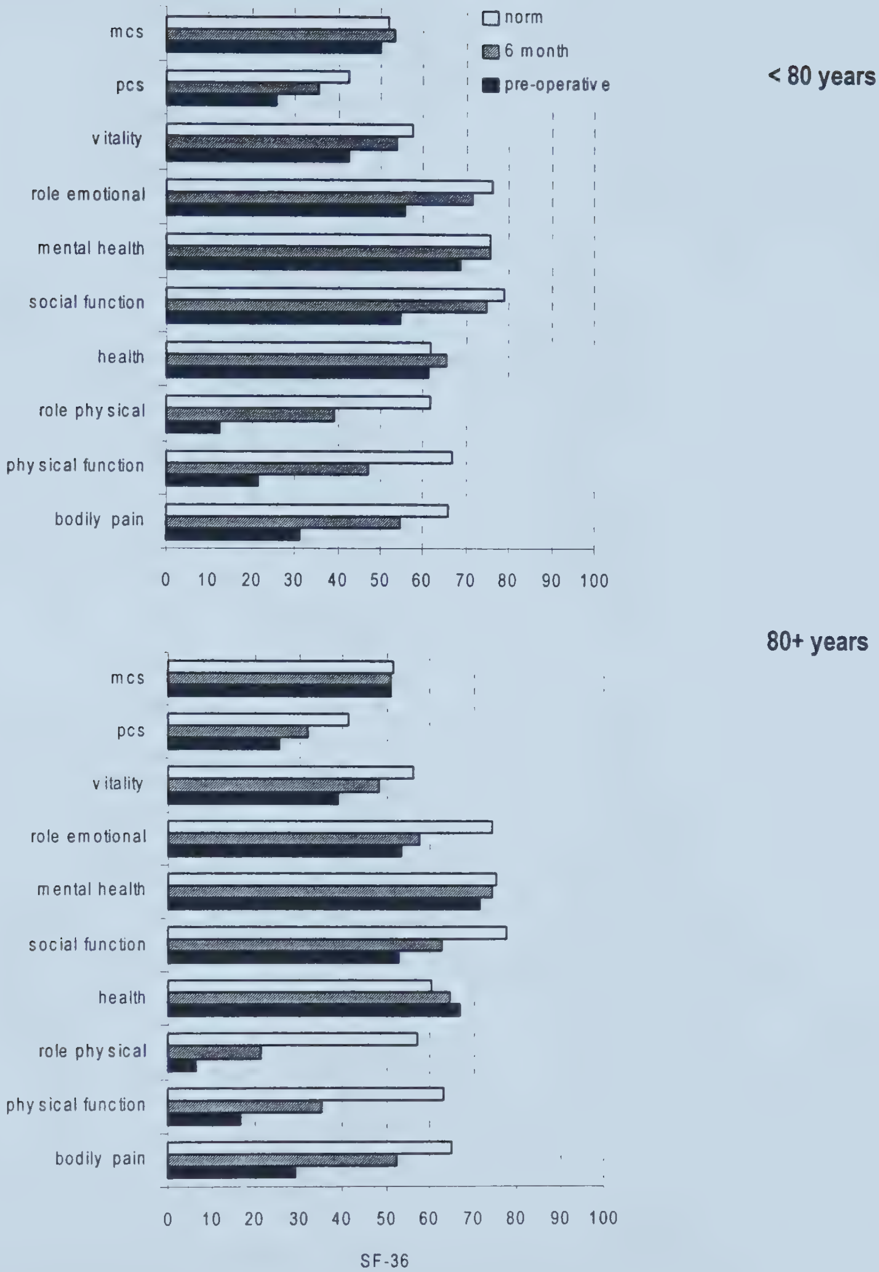
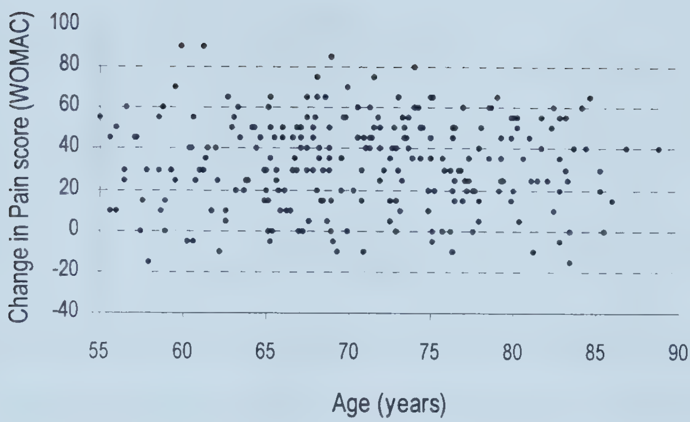


Figure 4-3: SF-36 pre-operative and 6 month scores of patients with total knee arthroplasties. Patients < 80 years old (*n* = 222) showed an improvement in all areas of the SF-36 (p = 0.001) (upper graph); whereas the older group (*n* = 35) did not change with areas pertaining to mental health: social function, mental health, role emotional and mental summary score (lower graph). Both age groups had similar pre-operative scores, yet the older group had a lower physical function, role function and social function scores at 6 months. See Appendix F for means and standard deviations.

Figure 4-4. Change in WOMAC scores for pain (upper graph) and function (lower graph) of total hip arthroplasties (n = 197). No clear trend can be identified with respect to age.



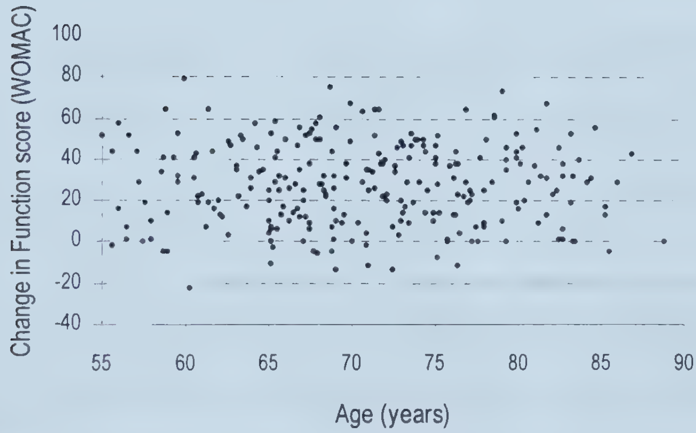


Figure 4-5. Change in WOMAC scores for pain (upper graph and function (lower graph) of total knee arthroplasties (n = 222). No clear trend can be identified with respect to age.

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CHAPTER 5

Predictive factors of pain and function after total hip and knee arthroplasties.

5.0 INTRODUCTION

For the majority of patients, total hip and knee arthroplasties (THA/TKA) are effective surgical procedures in providing pain relief and improved function, yet little is known about what factors predict these outcomes [NIH, 1994; Callahan et al, 1994]. Although surgeons and referring physicians agree that the primary indications for total joint arthroplasty are pain and dysfunction [Wright et al, 1995], the effect of secondary patient characteristics on pain and functional outcomes is undetermined. Because little is known about the determinants for THA or TKA, indications and contraindications for joint arthroplasties are poorly defined and practice patterns as well as utilization rates vary [Katz et al, 1996]. Further knowledge of determining factors will permit more efficient interventions with this patient population.

Whereas convincing evidence supports the effectiveness of THA and TKA [Hawker et al, 1998; Laupacis et al, 1993, Bayley et al, 1995; Rissanen et al, 1996; Ritter et al, 1995], multivariate techniques have seldom been performed to identify determinants of pain and functional outcomes for either THA or TKA [Sharma et al, 1996; MacWilliam et al, 1996; Braeken et al, 1997]. MacWilliam and colleagues (1996) reported that pre-operative function, comorbid conditions, and education were risk factors for poor outcomes of THA. Those patients with minimal pre-operative dysfunction, a greater number of comorbid conditions, and lower education did not benefit as greatly as other patients. In a retrospective chart review of patients undergoing elective THA, a higher body mass index was also related to poorer outcomes [Braeken et al, 1997]. Most studies have only examined medical and demographic data as possible determinants, but Sharma and colleagues (1996) reasoned that psychosocial factors such as motivation and social function were more influential than medical factors or baseline function in determining function after TKA. These early research findings are inconclusive and do not clearly identify patient-related factors that can predict pain relief or functional improvement after joint arthroplasties.

Although previous studies of joint arthroplasties have demonstrated that most patients substantially improve, approximately 15 to 20% do not report any improvement. [MacWilliam et al, 1996]. The purpose of this prospective cohort study was to identify patient-related factors that are predictive of pain and function gains seen after joint arthroplasties, with emphasis on those factors available to the clinician, including demographic, pre-operative medical, and peri-operative variables. Further information regarding patient characteristics predictive of pain and function would provide patients and surgeons with a realistic

estimation of their outcomes. Moreover, healthcare services could be utilized more efficiently if patients who require further support could be readily identified prior to surgery.

5.1 METHODS

5.1.1 Patient selection

A prospective community-based study of an inception cohort of patients recommended for either primary THA or TKA was conducted within a Canadian health region (Edmonton, AB). The study cohort had been assembled for another study examining waiting list times and subsequently, selection criteria were related to the time of placement on the list rather than the time of surgery. A consecutive cohort of patients placed on the waiting list from December 18, 1995 to January 24, 1997 for elective THA or TKA was identified. Patients were selected for this study if they were a) scheduled for primary total hip or knee arthroplasty, b) placed on the waiting list for at least 7 days before their surgery, c) residing within the health region, d) 40 years or older, and e) English-speaking. Patients undergoing hemiarthroplasties, revisions and emergency arthroplasties were excluded, in addition to those patients residing in long-term care institutions.

When patients' names appeared on the regional joint replacement waiting list, they were contacted to request participation in this study. Upon agreement, in-person interviews were arranged. Patients were informed they could withdraw from the study at any time without affecting their medical care. A written consent form was signed by all participants (Appendix A).

Based on the selection criteria, a total of 625 patients were identified within the health region. A further 84 (13%) patients refused or could not be contacted to request participation. Another 7 patients had their surgery prior to being contacted and 30 (5%) patients were lost to follow-up. This corresponds to a participation rate of 81%. The final study cohort was comprised of 504 patients, 228 and 276 who received THA and TKA, respectively. Among the participants, 492 (98%), 223 with THA and 269 with TKA had complete data for regression analyses.

All 26 orthopaedic surgeons who were practising at either one of the two hospitals within the health region gave permission for their patients to be contacted for participation in the study. An equal proportion of surgeries was performed at each hospital. No bilateral joint surgeries were performed during this study period. Indications for arthroplasties were pain, function, and/or deformity which did not respond to conservative management. Treatment was ensured by standardized caremaps for THA and TKA within the acute care, homecare, and community rehabilitation settings.

5.1.2 *Methods & Measures*

Pre-operative interviews were completed within 31 days prior to surgery. This assessment included a disease-specific questionnaire, *Western Ontario and McMaster Universities* (WOMAC) *Osteoarthritis Index* [(a)Bellamy et al, 1988, 1988; (b)Bellamy et al, 1988], a generic health status questionnaire, *SF-36 Health Survey* (SF-36) [Ware & Sherbourne, 1992; McHorney et al, 1994; Stewart et al, 1988], comorbidities, demographic characteristics, social support, and ambulatory status. Passive range of motion (PROM) of the involved joint was also measured at this time. The interview was repeated 6 months after surgery. Assessments were completed by one of three health professionals (two nurses and a physical therapist) who were not involved in patient care of the participants.

The dependent variables, joint-specific pain and functional outcomes, were measured using the WOMAC (Appendix A). This self-administered health questionnaire is designed to measure disability of the osteoarthritic hip and knee [(a) Bellamy et al, 1988; (b)Bellamy et al, 1988]. It is a responsive, reliable and valid instrument and has been extensively used to evaluate this patient population [Bombardier et al, 1995; (a)Bellamy et al, 1998]. The WOMAC provides aggregate scores for joint-specific pain (5 items) and physical function (17 items). Each item uses a five point Likert scale. Each subscale score was transformed to a range from 0 to 100 points, with a score of 100 indicating no pain or dysfunction. This type of transformation has been used by others to facilitate comparison between the WOMAC and SF-36 [Bombardier et al, 1995]

Health-related quality of life domains were measured with the SF-36 and pre-operative measures were treated as independent variables. This generic health measure is a self-administered 36 item questionnaire and takes approximately ten minutes to complete. Responses are aggregated into eight health dimensions: bodily pain, physical function, physical role function, mental health, emotional role function, social functioning, vitality, and general health perception (Appendix A). There is no global score. Scoring for each scale range from 0 to 100, with higher scores representing better health. Reliability and validity have been extensively evaluated in a variety of patient populations including total hip and knee arthroplasties and community dwelling elderly persons [Kantz et al, 1992; Bombardier et al, 1995; McHorney et al, 1994; Brazier et al, 1992; Lyons et al1994; Stucki et al, 1995; Mangione et al, 1993]. Moreover, the SF-36 is responsive to change in patients with joint arthroplasties [Bombardier et al, 1995].

Demographic information including age, gender, and education were collected at the baseline interview. Baseline medical information collected during the interview included contralateral joint involvement, previous joint arthroplasty, type of residence, and living arrangements. The number of self-reported chronic conditions were collected using a list of 23 items [Charlson et al, 1987] and presented as a simple additive score [MacWilliam et al, 1996]. Data regarding the type of implant fixation (cemented, hybrid

or cementless), the number and type of in-hospital complications (wound infection, dislocation, manipulation under anaesthesia, cardio-respiratory, peripheral/central nervous system involvement, urinary infection, acute confusion, blood loss requiring transfusion after surgery), and other medical information such as diagnosis were extracted from medical charts by two health professionals. Health services utilization data were extracted from the regional health databases.

5.1.3 Data analyses

The pain and function subscales of the WOMAC were examined separately in all analyses. The dependent variable was defined as the change in these two WOMAC subscale scores, that is, the difference between the pre-operative scores and the 6 month scores.

Initial descriptive statistics such as frequency distributions, means and standard deviations were calculated for all variables. If the variables were not normally distributed, medians and quartiles were calculated. Chi square tests and nonparametric analysis of variance (ANOVA) were used to identify differences between categorical variables, and Student's *t*-tests and ANOVA's were used to identify differences between continuous variables that were normally distributed. Nonparticipants were compared to participants using standard bivariate techniques to identify any systematic differences between the two groups.

Variables were initially collected on the basis of their clinical relevance as defined by published literature and healthcare professionals. In the context of the HRQoL model proposed by Wilson and Cleary (1995), clinical, functional, health perceptions, socio-demographics, HRQoL (disease specific and general) variables were measured to provide a comprehensive evaluation of joint arthroplasties. The independent variables were later categorized into three sets: a) demographic variables (age, gender, and education), b) medical / baseline variables (diagnosis, body mass index, number of comorbid conditions, previous joint arthroplasty, the pre-operative quality of life as measured by the SF-36, joint PROM, pre-operative ambulatory status, type of residence and living arrangements), and c) peri-operative variables (the number of in-hospital complications, type of implant fixation, surgeon, waiting times, and length of stay). Bivariate analyses for each of these variables were examined on the dependent variables. All independent variables that met the statistical level of less than 0.25 or were considered to be clinically meaningful were examined in the multivariate analysis.

Forward stepwise and forced entry multiple linear regressions were performed to identify those demographic, medical and surgical variables that could predict change in pain and function. Those independent variables that did not meet significance but were considered clinically meaningful such as age, gender, length of stay, and waiting times were force-entered into the model to control for potential

confounding effects. Model diagnostics such as residual plots were inspected to verify that the model assumptions of linearity were not violated. Collinearity among the independent variables was also inspected to assess for multicollinearity.

Logistic regression was also used to identify those variables associated with patients who showed no pain or functional improvement (WOMAC). Each dependent variable was dichotomized into two groups; those patients who improved and those who did not attain positive gains. Improvement was defined as a gain of at least 60% of the baseline standard deviation. Thus a gain of at least 10 points from the pre-operative scores for both pain and function scores was defined as improvement. This definition posed a potential problem for patients with pre-operative scores of 80 or greater because the WOMAC had a ceiling effect. Hence potential change for patients who had minimal pain or function was limited. To compensate for this effect, those patients with pre-operative scores of 80 or more who maintained a 6 month score of at least 80 were grouped with those having improved. If the 6 month score dropped below 80 for those patients, it was considered as no improvement. The independent variables that were considered for the multiple linear regressions were also considered for the logistic regressions.

Multiple comparison testing may be used when there are several independent comparisons in the study and the chance of finding a $p < 0.05$ increases with the number of tests. Adjustment for the multiplicity may be attempted with a complex and involved different comparisons and tests. Multiple inferences procedures such as the Bonferonni method are not recommended because they have low efficiency and poor accuracy [Rothman & Greenland, 1998]. Rather a more practical approach to deal with multiple comparisons is to recognize the error rate in multiple testing and to anticipate a P value smaller than 0.05 will occur by chance with1 in every 20 tests [Bailer & Mosteller, 1986]. Since comparisons were not entirely independent, we used a pragmatic approach to examine the statistical significant at both 0.05 and 0.01 levels.

Analyses were performed individually for THA and TKA outcomes because the magnitude of change varies with the type of joint replaced. All statistical testing was performed with two-tailed tests and at a 0.05 level of significance unless otherwise stated. Statistical analyses were performed using the SPSS software version 7.5.

5.2 RESULTS

5.2.1 Patient Characteristics

Nonparticipants (121) were similar to the study group (492) with respect to age; 68.4 ± 10.2 years as compared to 68.0 ± 10.0 years ($p=0.67$). No differences existed for the proportion of females in the nonparticipant (54%) and study groups (60%) ($p=0.24$). This was also true for the type of joint replaced; 40% of nonparticipants and 46% of the study group received THA ($p = 0.22$). Those patients who were lost to follow-up (30) or had incomplete data (8) were similar with respect to age, joint, gender, diagnosis, number of comorbid conditions, pre-operative health perception, previous joint replaced, and living arrangements to the final study cohort ($p>0.05$).

Among the 492 patients who had complete data for regression analyses, 223 and 269 patients received THA and TKA, respectively. The socio-demographic and baseline data are summarized in Table 5-1. The majority of patients were older women who were diagnosed with osteoarthritis. Of the 96% (473) patients who reported at least one comorbid condition, hypertension (HBP) and lower back pain (LBP) were the two most frequently reported conditions. Although all patients resided in the community, a greater proportion of women, 33% (99) lived alone than men, 14% (28) ($p< 0.001$).

Total hip arthroplasties Among the THA group, 33% (73) had the contralateral hip previously replaced, 38% (83) ambulated without assistive devices prior to surgery, and 76% (162) could walk outdoors. The mean pre-operative PROM for hip flexion was 77 ± 22 degrees which increased to 86 ± 17 degrees at 6 months post-operatively ($p< 0.001$).

This group also showed significant improvement in all 8 dimensions of the SF-36 ($p< 0.001$). The greatest changes as measured by the effect sizes were seen with bodily pain (2.39 ± 1.81) and physical function (1.70 ± 1.60); whereas, smaller changes were reported with general health (0.34 ± 0.97) and mental health (0.46 ± 0.83).

Total knee arthroplasties Approximately 25% (67) of the patients had the other knee previously replaced. The majority of this group ambulated independently for outdoor distances prior to surgery. Sixty-two percent of patients with knee involvement walked without any assistive devices and 94% (228) could walk outdoors. The mean knee flexion was 107 ± 15 degrees prior to surgery which decreased to 99 ± 14 degrees 6 months after surgery ($p< 0.001$).

As with the THA group, patients with TKA also showed improvement in HRQoL after surgery ($p< 0.002$). The greatest changes were seen with physical function and bodily pain; the effect sizes were 1.33 ±

1.39 and 1.30 ± 1.35, respectively. Smaller changes were seen with general health (0.13 ± 0.98) and emotional role limitation (0.26 ± 1.23).

Surgical characteristics The average length of stay was 7.4 ± 4.9 days for the THA group and 6.8 ± 2.1 days for the TKA group. As shown in Table 5-2, the majority of THA and TKA were hybrid, that is, only one prosthetic component was fixated with cement. Few THA were cemented, 8 (4%), and 44 (17%) of TKA were cementless. While 67% of patients had no in-hospital complications, the incidence of in-hospital complications was similar for THA and TKA groups, 0.34 per patient. The most frequently cited complications were urinary tract infection (32), and then thrombi/emboli (22). There were three deaths: two due to pulmonary embolism within one month of surgery and the other due to a non-related cause.

5.2.2 Outcomes of pain and function (WOMAC)

Total hip arthroplasties The mean baseline pain and function scores for patients with THA was 42.9 ± 16.1 and 38.4 ± 15.2. At 6 months, the mean pain score increased 42% to 84.6 ± 18.1, while function improved 38%, 76.3 ± 18.2 ($p < 0.001$). The magnitude of change as measured by the effect sizes was considered large for both pain (2.64 ± 1.30) and function (2.50 ± 1.42). The relationships between pre-operative scores and the amount of change for pain and function are seen in Figure 5-1. At the 6 month follow-up, 95% (211) patients with THA reported improvement of pain and 89% (196) had functional improvement of at least 10 points from their baseline scores.

Total knee arthroplasties Those patients with knee involvement reported mean baseline pain score of 43.2 ± 17.6 and functional score of 42.6 ± 17.3. Pain improved 33% to 76.1 ± 19.0 at 6 months and function improved 28% to 70.7 ± 18.2 ($p < 0.001$). The effect sizes for pain and function were also considered large, 1.87 ± 1.21 and 1.61 ± 1.15. Among the TKA group, 89% (240) patients showed positive gains with pain, 83% (222) reported functional improvement (Fig 5-1).

5.2.3 Determinants of pain

Multiple linear stepwise regression analyses could not identify any strong predictors of pain for either THA or TKA (Table 5-3 & 5-4). When controlling for age, gender, waiting time and LOS, low pre-operative bodily pain (higher SF-36 score) and a cementless prosthesis were associated with less pain relief. The number of comorbid conditions was also significant in predicting pain relief in patients with THA. Every additional comorbid condition reported by a patient resulted in a 1.7 point decrease in joint pain relief. Patients with cementless prostheses reported less pain relief than patients with at least one component cemented. When the independent variables that were not force-entered into the model were re-examined at a 0.01 level of significance, only the cementless variable did not reach this level for THA. All other

variables remained in the models. The explained variance in both models was considered low; 22% (THA) and 16% (TKA) of the variances were explained by these variables.

5.2.4 *Determinants of function*

After adjusting for age, gender, waiting time and LOS, those patients with minimal pre-operative joint pain (WOMAC), physical dysfunction (SF-36), and comorbid conditions were less likely to show functional improvement regardless of joint replaced (Table 5-5 & 5-6). All significant variables identified in the multiple regression models had small effects. For instance, a decrease in 10 points of pre-operative hip pain was associated with a 6 point increase of functional score change. Other factors associated with poor functional outcomes for THA included contralateral joint involvement and living alone. When variables were re-examined at a 0.01 level of significance, there were no changes to the proposed models. Thirty -one percent of the variance seen with functional change for THA was explained these variables; whereas, the variables identified for TKA explained 23% of the variance.

5.2.5 *Risk factors for poor outcomes*

Tables 5-7 and 5-8 show the variables considered for assessing the risk for poor outcomes of pain and function; that is, predicting the risk of not improving. As with the multiple linear regression models, age, gender, waiting time and LOS were forced entered into the models to control for these effects. The odds of not experiencing any pain relief after a THA was 1.4 times greater for every comorbid condition; whereas patients with cementless TKA were 3.5 times more likely not to improve. No other variables such as pre-operative bodily pain were significant in predicting pain relief. The number of comorbid conditions was not a significant variable for TKA pain at a 0.01 level of significance. Approximately 11% of the variation in model containing the intercept was explained by the model including implant fixation and comorbid conditions for TKA; whereas 10% of the variation was explained by the model containing a number of comorbid conditions for THA (Appendix C). Given these low values, the risk of not improving was not well explained by these variables.

A similar picture was seen with predicting poor functional outcomes. Pre-operative hip pain and the number of comorbid conditions were significant variables in predicting function for THA (Table 5-8). For every comorbid condition reported, a patient was 1.6 times at risk of showing no functional improvement. Only 20% of the variation in the model containing the intercept only was explained by the model with these covariates. No clear variables could identify the risk of poor functional outcome for TKA, although pre-operative knee pain had a small but significant effect. Variables that met the 0.05 level of significance also met the more stringent level of 0.01. Perhaps more importantly, the variation explained in this model was

only 5%. Consequently, the risks of not improving after either THA or TKA were poorly explained by these variables.

5.3 DISCUSSION

Findings from this community-based cohort are consistent with the good results reported in hospital and surgeon-based cohorts [Laupacis et al, 1993; Bayley et al, 1995; Sharma et al, 1996]. Alternately, 5% of patients with THA and 11% of the TKA group did not report any pain relief. A larger proportion reported no functional improvement for either THA (11%) or TKA (17%). Because this study cohort was community-based, it was believed to be representative of general practice patterns. Although previous studies have demonstrated good results, determinants of pain and functional outcomes have rarely been examined.

Multiple linear or logistic regression analyses did not identify any one single clinical factor that could predict the outcomes of either pain or function. Patients who reported less pain relief or functional improvements tended to have minimal pre-operative bodily pain and/or minimal dysfunction, regardless of the joint replaced. This finding was consistent with previous studies that found patients who had minimal pre-operative pain and function, had less chance of improving [MacWilliam et al, 1996; Braeken et al, 1997]. Upon further examination, this finding was most likely attributable to a ceiling effect of the questionnaire. To compensate for this effect, patients' scores were redefined and categorized into two groupings with respect to improvement and subsequently, logistic regression analyses were performed. Utilizing this approach, pre-operative bodily pain (SF-36) and physical function (SF-36) were not significant factors in predicting the risks of poor outcomes.

Alternate methods of compensating for a ceiling effect of the WOMAC would have been to use relative measures such as the difference of the pre-operative and 6 months scores relative to the pre-operative score. Another method would have been to transform the data to odds ratio. Although these suggestions are viable, clinical interpretation is more complex. Interpretation of the difference between pre-operative and 6 month scores which have been used by others [MacWilliam et al, 1996] was considered a more straightforward, practical means of evaluating this data.

Findings from this study may have further clinical implications with respect to the effects of such controversial factors as weight and comorbid conditions. Since few studies have specifically examined the association of these factors on pain and functional outcomes, their effects remain ambiguous in the literature. Our results concurred with Hawker and colleagues (1998) that weight does not have a negative influence on pain and function. Much controversy exists on the effect of obesity because of the high mechanical failure of the prosthesis and potential increased post-operative complications. While some studies reported that higher body mass index was associated with greater post-operative pain and

dysfunction [Braeken et al, 1997], others have discounted obesity as an adverse factor [Hawker et al, 1998, Stern & Install, 1990; Chan & Villar, 1996]. Multivariate analyses did not reveal BMI as a significant covariate in predicting either pain or function for THA or TKA. Body mass index was a significant factor when unadjusted for functional outcome of patients receiving THA, yet when adjusted for other baseline and surgical factors, BMI did not have a significant effect on pain or function. This finding and the small size of the regression coefficient suggest that any effect from BMI is likely to be small.

The effect of the comorbid conditions variable was small but significant on functional change score; that is, every additional comorbid condition was reflected in a decrease of approximately two points. Previous studies have found that comorbid conditions had a large effect on both pain and functional outcomes in THA [MacWilliam et al, 1996], as well as being predictive of post-operative complications [Imamura & Black, 1998] and longer hospital stays [Wang et al, 1998]. Alternately, others have reported that comorbid conditions have little effect on the change of health status after THA [Imamura & Black, 1998]. Findings from this study may contrast with previous studies because of the lack of standardized methods to prospectively record comorbid conditions.

Although the effect of comorbid conditions was small, the recognition of comorbid condition in the context of HRQoL and joint arthroplasties is necessary. As proposed by Wilson and Cleary (1995), a multitude of factors affects HRQoL. Given Wilson and Cleary's model of HRQoL, other health problems will affect the overall function and health status of a person. In turn, when evaluating pain and functional changes after joint arthroplasties, other factors such as comorbid conditions need to be recognized in the context of the amount of change a person is expect to achieve. The findings from this study indicate that comorbidity is an independent factor that has a small but significant effect on the amount of functional improvement to be gained.

Further debate centres upon implant fixation. While some clinical trials have identified that cementless prostheses are associated with greater pain, other studies have described the technical successes [Callahan et al, 1994; Callaghan et al, 1995; Campbell et al, 1992; Heekin et al, 1993]. Previous authors have reported a higher incidence of thigh pain with cementless THA which steadily increased over a two year follow-up [Campbell et al, 1992]. Results from this study suggest that cementless prostheses are associated with less pain relief over 6 months.

A myriad of factors likely affect the outcomes of pain and function; however, it should be emphasized these outcomes relied upon the participants' perception of pain and function. It is unknown what other factors such as expectations or motivation affect these responses. Limited evidence have reported that psychosocial variables contribute more than medical and baseline variables in predicting functional outcomes after TKA [Sharma et al, 1996]. Conversely, self-reported measures of function and

general health do not appear in be inferior with respect to sensitivity of change, reliability and validity of clinical performance measures [Myers et al, 1993].

One caveat should be recognized with respect to these results. Favourable outcomes of joint arthroplasties not only include pain relief and improved function, but also the longevity of the prosthesis. Patients in this study group were followed for 6 months which was insufficient time to determine the revision rates.

5.4 CONCLUSIONS

Much of the improvements seen with pain and function after joint arthroplasties remain unexplained. No single demographic or clinical factor can clearly identify the amount of pain relief or functional improvement reported. Comorbid conditions did exert a small negative effect on pain in THA and function in THA and TKA, that is, a greater number of comorbid conditions was reflected in less improvement. For more explicit answers to emerge, standardized measures of comorbid conditions need to be developed with respect to joint arthroplasties. Although other factors intrinsic to the patient (e.g. expectations, motivation) were not evaluated in this study, they may warrant further examination. Our results suggest that most arthroplasties are appropriately performed since the majority of patients improve, but health status data available to clinicians are not helpful in identifying those patients who will not improve.

Table 5-1: Demographic and medical characteristics of patients with total hip and knee arthroplasties.

	Hips (n = 223)			Knees (n = 269)		
female gender	134 (60%)			159 (59%)		
osteoarthritis	209 (95%)			250 (94%)		
education $\geq$ high school	136 (61%)			145 (54%)		
previous arthroplasty	73 (33%)			67 (25%)		
living alone	62 (28%)			65 (24%)		
	mean	standard deviation	range	mean	standard deviation	range
age (yrs)	68.2	11.1	40 - 89	69.2	9.2	40 - 89
comorbidity	3.4	2.2	0 - 13	3.5	2.0	0 -11
body mass index (kg / m^2)	29.3	5.5	18.1 - 49.4	31.6	5.9	20.3 - 57.1

Table 5-2: Peri-operative characteristics.

	Total hip arthroplasties (n = 223)	**Total knee arthroplasties** (n = 269)
fixation		
cementless	82 (37%)	44 (17%)
hybrid	133 (60%)	152 (57%)
cemented	8 (3%)	69 (26%)
complications- none	151 (68%)	177 (67%)
	mean $\pm$ standard deviation	mean $\pm$ standard deviation
waiting times (days)	95.1 $\pm$ 79.3	105.2 $\pm$ 90.2
length of stay (days)	7.4 $\pm$ 4.9	6.8 $\pm$ 2.1

Table 5-3. Multiple linear regression: Pain outcome of total hip arthroplasty. *

Variables	**Unadjusted** *Unstandardized coefficient*	*Standardized coefficient*	*CI*	p	**Adjusted** *Unstandardized coefficient*	$R^2 = 0.22$ *Standardized coefficient*	*CI*	p
intercept					56.71		(34.70, 78.73)	<0.001 **
age	0.18	0.08	(-0.06, 0.43)	0.15	-0.03	-0.001	(-0.29, 0.28)	0.99
female gender	7.64	0.18	(2.20, 13.12)	0.01 **	6.21	0.15	(1.01, 11.41)	0.02 **
waiting time	-0.01	-0.05	(-0.05, 0.02)	0.46	0.01	0.03	(-.02, 0.04)	0.61
length of stay	0.22	0.05	(-0.33, 0.77)	0.43	0.35	0.08	(-0.15, 0.88)	0.18
pre-operative bodily pain (SF-36)	-0.52	-0.38	(-0.68, -0.35)	<0.001 **	-0.53	-0.39	(-0.70, -0.36)	<0.001 **
comorbid conditions	-0.58	-0.06	(-1.78, 0.63)	0.35	-1.67	-0.18	(-2.84, -0.51)	0.01 **
cementless	-8.47	-0.19	(-14.17, -3.11)	0.04 **	-7.09	-0.17	(-13.72, -0.46)	0.04 **

* dependent variable = difference between pre-operative and 6 month WOMAC pain score.
** statistically significant $p< 0.05$
CI = 95% confidence interval

Table 5-4. Multiple linear regression: Pain outcomes of total knee arthroplasty. *

Variables	**Unadjusted**				**Adjusted**	$R^2 = 0.16$		
	Unstandardized coefficient	*Standardized coefficient*	*CI*	p	*Unstandardized coefficient*	*Standardized coefficient*	*CI*	p
intercept					35.27		(13.89, 56.65)	0.001 **
age	0.24	0.10	(-0.04, 0.51)	0.09	0.28	0.12	(0.06, 0.54)	0.04 **
female gender	3.74	0.09	(-1.43, 8.90)	0.16	-0.65	-0.01	(-5.59, 4.29)	0.80
waiting time	0.01	0.04	(0.02, 0.04)	0.48	0.01	0.06	(-0.01, 0.04)	0.29
length of stay	-1.43	-0.13	(-2.78, -0.08)	0.04 **	-1.37	-0.12	(-2.64, -0.09)	0.04 **
pre-operative bodily pain (SF-36)	-0.35	-0.29	(-0.49, -0.21)	<0.001 **	-0.39	-0.32	(-0.52, -0.25)	<0.001 **
cementless	-11.30	-0.20	(-18.03, -4.57)	<0.001 **	-9.70	-0.17	(-16.11, -3.29)	0.003 **

* dependent variable = difference between pre-operative and 6 month WOMAC pain score.

** statistically significant $p < 0.05$

CI = 95% confidence interval

Table 5-5. Multiple linear regression: Functional outcome of total hip arthroplasty. *

Variables	**Unadjusted** *Unstandardized coefficient*	*Standardized coefficient*	*CI*	p	**Adjusted** *Unstandardized coefficient*	$R^2 = 0.31$ *Standardized coefficient*	*CI*	p
intercept					55.06		(35.68, 74.45)	<0.001 **
age	0.15	0.08	(-0.11, 0.41)	0.25	0.44	0.22	(0.19, 0.69)	0.001 **
female gender	4.57	0.10	(-0.13, 10.42)	0.13	5.12	0.12	(-0.13, 10.38)	0.06
waiting time	-0.03	-0.12	(-0.07, 0.003)	0.07	-0.02	-0.08	(-0.05, 0.01)	0.15
length of stay	-0.10	-0.02	(-0.69, 0.48)	0.73	-0.16	-0.04	(-0.68, 0.37)	0.56
pre-op joint pain (WOMAC)	-0.53	-0.39	(-0.70, -0.36)	<0.001 **	-0.61	-0.45	(-0.77, -0.45)	<0.001 **
comorbid conditions	-1.23	-0.13	(-2.53, .061)	0.06	-2.60	-0.27	(-3.79, -1.41)	<0.001 **
lives alone	-7.61	-0.16	(-13.96, -1.26)	0.02 **	-11.01	-0.23	(-17.05, -4.99)	<0.001 **
contralateral involvement	-5.09	-0.15	(-9.68, -0.50)	<0.001 **	-6.180	-0.18	(-10.12, -2.25)	0.002 **

* dependent variable = difference between pre-operative and 6 month WOMAC function score.
** statistically significant $p < 0.05$
CI = 95% confidence interval

Table 5-6. Multiple linear regression: Functional outcomes of total knee arthroplasty. *

Variables	**Unadjusted** *Unstandardized coefficient*	*Standardized coefficient*	*CI*	p	**Adjusted** *Unstandardized coefficient*	$R^2 = 0.23$ *Standardized coefficient*	*CII*	p
intercept					44.65		(24.68, 64.62)	<0.001 **
age	0.17	0.08	(-0.09, 0.44)	0.19	0.26	0.12	(0.02, 0.50)	0.04 **
female gender	4.49	0.11	(-0.38, 9.36)	0.07	0.05	-0.01	(-4.56, 4.67)	0.98
waiting time	-0.01	-0.05	(-0.04, 0.02)	0.40	-0.01	-0.03	(-0.03, 0.02)	0.62
length of stay	0.28	0.25	(0.15, 0.42)	<0.001 **	-0.87	-0.08	(-2.04, 0.30)	0.15
pre-op joint pain (WOMAC)	-0.45	-0.40	(-0.57, -0.32)	<0.001 **	-0.42	-0.37	(-0.56, -0.28)	<0.001 **
comorbid conditions	-0.54	-0.05	(-0.75, 1.83)	0.44	-1.70	-0.17	(-2.86, -0.55)	0.004 **
pre-op physical function (SF-36)	-0.34	-0.30	(-0.47,-0.21)	<0.001 **	-0.19	-0.17	(-0.32, -0.05)	0.007 **

* dependent variable = difference between pre-operative and 6 month WOMAC function score.
** statistically significant $p < 0.05$
CI = 95% confidence interval

Table 5-7. Logistic regression to predict no pain relief for total hip and knee arthroplasties.

	Hips				Knees			
	Unadjusted		Adjusted		Unadjusted		Adjusted	
Variables	*OR+*	*CI**	*OR+*	*CI**	*OR+*	*CI**	*OR+*	*CI**
age (years)	0.97	0.92, 1.02	0.94	0.88, 1.00	0.96	0.93, 1.00	0.95	0.91, 1.00
gender (female)	0.93	0.28, 3.01	0.65	0.18, 2.29	0.61	0.28, 1.32	0.69	0.30, 1.62
waiting time (3 to 6 mon)	2.08	0.61, 7.11	2.07	0.58, 7.37	0.73	0.29, 1.85	0.81	0.30, 2.17
(> 6 mon)	0.83	0.10, 7.20	0.56	0.05, 6.20	0.97	0.33, 2.79	1.21	0.39, 3.76
length of stay (days)	0.95	0.74, 1.21	0.94	0.69, 1.30	1.121	1.00, 1.45	1.12	0.91, 1.39
number of comorbid conditions	1.27 **	1.03, 1.58	1.41 **	1.10, 1.80	1.11	0.92, 1.33	1.21 **	1.01, 1.47
pre-operative bodily pain (SF-36)	1.02	0.98,1.06	not included		1.00	0.98, 1.02	not included	
cementless	3.70 **	1.08, 12.70	not included		3.53	1.49, 8.35	3.42 **	1.40, 8.38

\+ *OR* = odds ratio
* *CI* = 95% confidence interval
** statistically significant

Table 5-8. Logistic regression to predict no functional improvement for total hip and knee arthroplasties.

	Hips				**Knees**			
	Unadjusted		**Adjusted**		**Unadjusted**		**Adjusted**	
Variables	*OR+*	*CI**	*OR+*	*CI**	*OR+*	*CI**	*OR+*	*CI**
age (years)	0.97	0.93, 1.01	0.94 **	0.88, 0.98	1.00	0.96, 1.03	1.00	0.96, 1.04
gender (female)	0.71	0.30, 1.68	0.73	0.26, 2.08	0.70	0.37, 1.33	0.87	0.43, 1.74
waiting time (3 to 6 mon)	1.63	0.64. 4.17	1.71	0.59, 4.97	1.23	0.60, 2.53	1.06	0.49, 2.29
(> 6 mon)	1.17	0.31, 4.42	0.69	0.12, 4.00	1.35	0.57, 3.19	1.42	0.58, 3.49
length of stay (days)	1.00	0.92, 1.09	1.01	0.89, 1.14	1.13	0.96, 1.32	1.15	0.97, 1.37
pre-operative joint pain (WOMAC)	1.03 **	1.00, 1.06	1.05 **	1.01, 1.09	1.03 **	1.01, 1.05	1.03 **	1.01, 1.05
pre-operative physical function (SF-36)	1.03 **	1.01, 1.05	not included		1.01	0.99, 1.03	not included	
pre-operative social function (SF-36)	1.01	0.99, 1.02	not included		1.01	0.99, 1.02	not included	
lives alone	1.78	0.73, 4.36	not included		1.29	0.63, 2.63	not included	
previous replacement	2.02	0.80, 5.10	not included		1.57	0.78, 3.16	not included	
contralateral joint involvement	3.07	0.74, 12.72	not included		0.90	0.25, 3.28	not included	
number of comorbid conditions	1.29 **	1.09, 1.54	1.60 **	1.25, 2.05	1.10	0.94, 1.28	not included	

+ *OR* = odds ratio
* *CI* = 95% confidence interval
** statistically significant

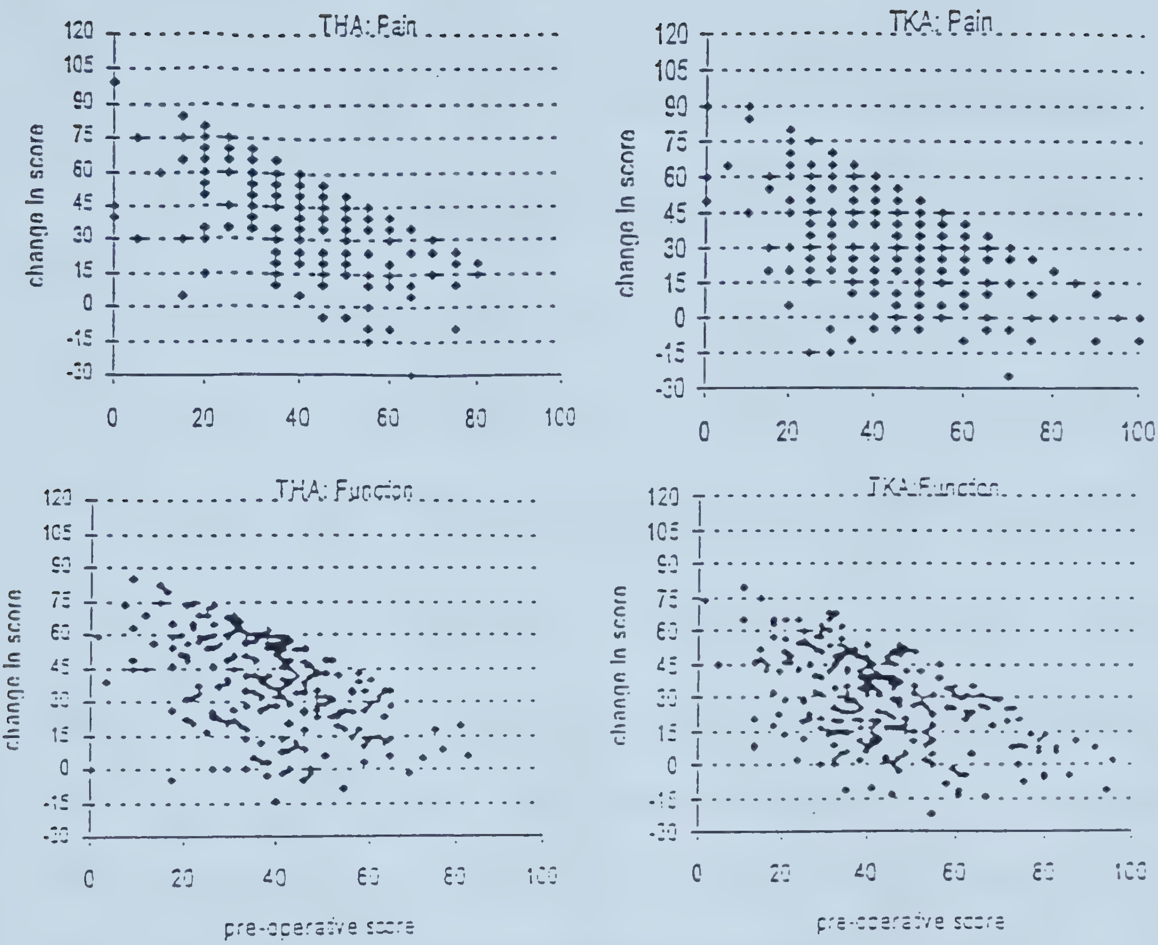

Figure 5-1. Distribution of change in pain (upper graphs) and function (lower graphs) as compared to pre-operative scores for THA and TKA groups. A linear relationship is seen with the change in score and the pre-operative values; that is a higher pre-operative value (better status) is associated with a smaller change in scores. This most likely is due to the ceiling effect of the WOMAC. Patients with higher scores cannot demonstrate as great of change as those patients with lower pre-operative scores.

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CHAPTER 6

GENERAL DISCUSSION and CONCLUSIONS

6.0 Overview

Total hip and knee arthroplasties are common orthopaedic surgeries performed in the elderly population to relieve pain and improve function. Over the past two decades the utilization rates have been steadily increasing because of an aging population and technical/surgical advancements. Although the utilization rates have increased, relatively little research has examined outcomes of joint arthroplasties, specifically, HRQoL outcomes, the effect of age on these outcomes and determinants of pain and function. In this thesis, the effectiveness of THA and TKA was examined with respect to pain and function. Given the lack of generalizability within published findings and the prevalence of joint arthroplasties, this present research evaluated joint arthroplasties in an inception community-based cohort. It was assumed findings from this study were reflective of general practice patterns and were generalizable to a major proportion of this patient population.

To date, no studies have prospectively followed this type of cohort within a joint arthroplasty patient population. This study is unique in its patient population and thorough description of not only peri-operative data, but also patient-based data and health services utilization information. While most studies have only provided acute care hospital information, data from this study were collected from a variety of sources: patients, acute care hospitals, rehabilitation facilities and community rehabilitation services, to ensure accuracy and comprehensiveness of the data.

6.1 Health-related quality of life outcomes

The results presented in Chapter 3 affirm that joint replacements are effective surgical procedures for the majority of patients in relieving pain and improving function. While large gains were seen with pain and function, more modest changes were seen in other health dimensions such as mental health and vitality. Findings from clinical and cross-sectional studies have demonstrated that patients improve after joint arthroplasties [Bayley et al, 1995; Rissanen et al, 1995; Ritter et al, 1995; MacWilliam et al, 1996]. The generalizability of these studies is, however, limited for two basic reasons: a) the study design used to evaluate joint arthroplasties, and b) the limitations of patient selection. Many studies have been conducted as a part of clinical trials evaluating the outcomes of specific prostheses in highly selected patients [Laupacis et al, 1993], as opposed to population-based inception cohorts undergoing usual care. In addition, findings reported in the literature are frequently based on results from heterogeneous patient groups; that is, patient groups varied with respect to age, joint, and type of surgery (primary vs. revision)

[Rissanen et al, 1996; Ritter et al, 1995; McGuigan et al, 1995; Bayley et al, 1995]. These reasons may account for the inconsistent findings reported in the literature and the ambiguity regarding patient appropriateness for surgery [Wright et al, 1995]

As proposed in the HRQoL model by Wilson and Cleary, a multitude of variables affect HRQoL and subsequently advocate the use of generic and specific health questionnaires. Because the findings from this study were evaluated using both generic and specific outcomes in a community-based cohort, the results were assumed to be reflective of general practice patterns and could be generalized to the patient population.

The improvements reported here were considered large, in excess of one standard deviation from the baseline. A few trends can be concluded from these findings. Firstly, greater changes were reported with pain than function, while moderate changes were reported in other health related quality of life areas. Secondly, while large gains were seen with bodily pain and physical function (SF-36), the 6 months scores were not comparable to the age:sex adjusted general population. For the most part, patients were already at norm-based levels for those HRQoL dimensions which had modest improvements. Given those patients were near the population mean values, the modest changes in those HRQoL dimensions were expected. Lastly, changes that were seen with pain, function and overall health status were joint-dependent. Although the TKA group achieved less pain relief and functional improvement than the THA group, implications for further research would include a longer follow-up period for this TKA group to determine whether they eventually achieve similar results as the THA group. Because of the different amount of change seen with THA and TKA groups, findings from this study recommend that joint arthroplasties should be evaluated with respect to the type of joint replaced.

Effectiveness of joint arthroplasties, however, should be considered in light of revision rates. Given the favourable outcomes of this study, the longevity of the prosthesis will, no doubt, affect the long term pain and functional outcomes. Further follow-up of this particular cohort would provide valuable information to interpret these outcomes.

6.2 Age and joint arthroplasties

The results from the second paper did not reveal that age alone was a significant factor of pain and function, nor were higher complication or mortality rates found in the older groups. These findings have particular clinical relevance to surgeons because there appears to be a selection bias of candidates for surgery. That is, surgeons selected only healthy older patients for joint arthroplasties in this study. This observation does not appear to be unique to this research. In a review of Medicare beneficiaries, Katz and colleagues (1995) found that the utilization rates for TKA had increased, but the mean age did not change.

Furthermore, a survey of orthopaedic surgeons found a lack of consensus among surgeons regarding secondary characteristics such as age in determining suitable candidates for surgery [Wright et al, 1995]. Clinically, age is a factor in determining whether a patient receives surgery.

Previous literature suggested that older patients do not achieve similar functional levels and experience higher complication and mortality rates [Newington et al, 1990; Petersen et al, 1989; Phillips et al, 1987; Levy et al, 1995]. For instance, in a retrospective review of 107 medical charts patients 80 years or older, Newington and colleagues (1990) reported a 4% mortality rate at one year; however, only less than half of patients were followed. Furthermore, 15% (n= 17) experienced acute hip dislocations. Although these rates were not compared to a younger group, these findings led the authors to conclude that older patients have more post-operative complications and higher mortality.

There are a few reasons why the results from the present study did not support previous findings. First, earlier studies were typically small descriptive studies of older patients with no comparison groups. This study was a larger, prospective study with standardized peri-operative care. Moreover, the results from the older group were compared to a younger group which was representative of the average age that patients receive joint arthroplasties. Second, all of the previous studies except for two [Brander et al, 1997; Zicat et al, 1993] examined complication rates only for THA. If complication and mortality rates are higher in older patients with THA, this cannot be generalized to the TKA population. This study examined THA and TKA groups separately and did not find complication rates higher than the younger comparison groups. Moreover, the type of complications was not different for the age groups.

Because the majority of patients who receive joint arthroplasties are between 55 and 79 years, this study compared the outcomes of patients 80 years and older to this younger group. The magnitude of change reported in both age groups was similar. Furthermore, when the effect of other variables such as pre-operative functional status or pain were statistically controlled, age did not effect the outcome. Given that elderly patients achieve similar outcomes as their younger counterparts, further research is needed to determine whether elderly patients could be discharged directly home rather than transferred to a rehabilitation centre.

One may argue that age group differences were not seen because this was a healthy older cohort; the number of comorbid conditions was similar for both age groups. Comorbid conditions are age related; with increasing age, a greater number of comorbid conditions are expected to exist [Verbrugge et al, 1989]. Measurement of comorbid conditions was a limitation of this study. A need to standardize methods of defining and recording comorbid conditions is recognized within the joint arthroplasty literature [Imamura et al, 1998], but few measures have been developed or used. Moreover, the measures that have been developed have been weighted with respect to mortality, not function, and are not applicable in studies

which examine pain and function [MacWilliam et al, 1996]. For this reason, the number and type of comorbid conditions were used in this study rather than previously recognized indexes.

Comorbid conditions are well recognized as important factors in determining surgical outcomes, yet the lack of standardized measures limits the estimation the true impact of comorbid conditions on joint arthroplasties. Nevertheless, findings from this study should provide surgeons with quantitative evidence to encourage older patients with unrelenting joint pain and debilitating function to undergo joint arthroplasties.

6.3 Determinants of pain and function

Although age alone was not a significant factor in determining the outcomes of joint arthroplasties in patients 80 years or older, the relationships among medical, socio-demographic, and peri-operative factors were explored through multivariate techniques to identify those clinical factors predictive of pain and function.

Initial variables were selected on the basis of previous published studies, clinical relevance, and accessibility of data to the clinician. These variables were described in the contextual HRQoL model proposed by Wilson and Cleary (1995). In this model, they proposed five levels of patient outcomes; biologic and physiologic, patient's symptoms, function, general health perceptions, and overall quality of life. Although the model does not detail the complex and dynamic relationships that determine one's health status, it does attempt to link clinical and HRQoL concepts. Clinical variables such as joint range of motion and implant fixation had surgical implications on the overall outcome, while variables concerned with function (physical, mental, emotional, and social) and health perception were also perceived to affect the pain and functional outcomes. Because of the inherent complexities of pain and function, analyses of these variables could not be reduced to a linear path. Rather, multivariate analyses was a statistical approach that could simultaneously evaluate these multiple factors.

This present study used multivariate analyses to identify clinical predictors. Given the variety of variables: biologic, function and health perception, it was surprising that relatively few patient characteristics were associated with pain and functional change. Numerous factors such as obesity, age, and comorbid conditions have been reported to exert adverse effects on joint arthroplasty outcomes [Newington et al, 1990; Petersen et al, 1989; Braeken et al, 1997; MacWilliam et al, 1996]. Age and obesity did not have adverse effects on pain or function; however, comorbid conditions did exert a negative effect on pain in THA and function in THA and TKA. That is, a greater number of comorbid conditions was reflected in less improvement. Although the literature recognizes the importance of comorbid conditions with surgery, only one other study reported the significance of comorbid condition in pain and function after THA [MacWilliam et al, 1996]. No studies have established an association with comorbid conditions and TKA. This is most

likely because few studies have measured comorbid conditions [MacWilliam et al, 1996; Greenfield et al, Sharma et al, 1996].

Cementless prostheses also exerted a negative effect on pain for both THA and TKA. Small clinical trials have reported more thigh pain with cementless THA [Bukart et al, 1993]. One retrospective study reported cementless prosthesis as a potential factor predictive of poor pain relief in THA [Braeken et al, 1997]; however, no studies have examined whether there is an association of cementless prosthesis and pain in TKA. The findings here suggest that the type of prosthesis, no matter the type of joint replaced, will affect the short-term outcome of pain.

Pre-operative joint pain exerted a negative influence on function; that is, greater joint pain prior to surgery was reflected in more improvement. This finding has direct clinical applicability. Concern should be expressed towards those patients with minimal joint pain and their expectations of surgery. These patients most likely will not achieve a better functional level. Extensive education regarding the outcomes needs to be explained to these patients prior to surgery.

The majority of variances seen in the outcomes could not be explained by these variables suggesting that pain and function are inherently complex. Given the dynamic relationships proposed by Wilson and Cleary (1995), it may be that indirect and direct relationships need to be evaluated to identify those predictive variables. Although multiple linear regression can only examine direct relationships, alternate analyses of direct and indirect relationships may reveal determinants of pain and function.

Further research is needed to examine not just demographic or medical variables, but also intrinsic factors such as patient expectations and motivations. The variables examined here did measure patients' perceptions and satisfaction, but did not evaluate expectations which affect a patient's overall health state. Intrinsic individual characteristics may warrant further examination in the outcome of pain and function within the joint arthroplasty population. As larger and more comprehensive studies are undertaken with this patient population, further information will be generated to gain a better understanding of factors that influence pain and functional outcomes

6.4 Concluding remarks

In an era of healthcare accountability, quantitative evidence is fundamental to demonstrate that an intervention such as joint arthroplasty is effective and efficacious. Joint arthroplasties, in most cases, are elective surgeries performed because of arthritis, a chronic disease. In spite of the favourable results and clinical popularity, surgical rationalization is needed. While variation in utilization rates and practice patterns reflect the ambiguity of patient selection, those patients who are at risk of poor outcomes need be identified prior to surgery so they may receive further support.

This patient group was representative of the general joint arthroplasty population because it was an inception community-based cohort with no selection or participation biases revealed with respect to age, gender, joint replaced or hospital site. This study did not include patients from rural settings and, therefore, these findings can be generalized only to urban populations. Lastly, the longevity of the prosthesis and the impact on overall function remain unanswered in this study group because of the short follow-up period.

The contribution of this study to the joint arthroplasty body of knowledge supports the pain and functional improvements seen, but provides substantial evidence regarding a) the amount of change to be expected after surgery, b) the effects of age , and c) the determinants of pain and function. While clinical studies have examined pain and functional outcomes in joint arthroplasties, the findings presented in this study will provide more extensive information to the joint arthroplasty patient population.

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APPENDIX A

INFORMATION SHEET

CONSENT FORM

QUESTIONNAIRE

INFORMATION SHEET

Hip and Knee Replacement in the Capital Health Region

Principal Investigators:	Dr. Don Voaklander
	Dr. Maria Suarez-Almazor
Co-investigators:	Dr. Bill Johnston
	Mr. Gordon Kramer
	Dr. Lynn Redfern

Background: As our population ages, chronic disease which interfere with years of life in good health and with the ability to function independently are if increasing concern. Mobility is an important factor in independent living. The significant number of persons suffering from arthritis, an aging population, and the good results attained with joint replacement surgery have resulted in a growing demand for such surgery. However, waiting times for joint replacement surgery have become a concern for the public in recent years as the demand grows.

Purpose: You are being asked to participate in this research study. The purpose of this study is to identify factors related to waiting times for hip and knee replacement surgery.

Procedures: Participating in this study will involve three assessments: today, just prior to surgery, and at 6 months after surgery. At these times you will be asked to complete surveys regarding your health, daily activities, and quality of life. Each assessment will take about thirty minutes. The first questionnaire will be administered in you home, while the follow-up questionnaires will be administered either in your home or at the pre-admission surgery clinic.

Possible Benefits: There may not be direct benefits to you for being in this study; however, it is expected that once the study is completed, the results will help caregivers understand who has been receiving surgery with the least wait.

Possible Risks: There is no risk involved in this study.

Confidentiality: Personal records relating to the study will be kept confidential. Any report coming from this research will not give your name.

You are free to withdraw from the research study at any time and your continuing medical care will not be affected in any way. If the study is discontinued at any time, the quality of your medical care will not be affected.

Please contact any of the individuals identified below if you have any questions or concerns.
Dr. Don Voaklander at (403)492-5099 or Dr. Maria Suarez-Almazor at (403)492-9589

CONSENT FORM (To be completed by the participant)

Title of the project: **Hip and Knee Replacement in the Capital Health Region**

Principal Investigators:	Don Voaklander, Ph.D. Maria Suarez-Almazor, Ph.D.
Co-investigators:	Dr. Bill Johnston, M.D. Mr. Gordon Kramer, M.H.S.A. Dr. Lynn Redfern, Ph.D.

Please circle **YES** or **NO** in response to each of the following questions.

Do you understand that you have been asked to be in a research study?	**YES**	**NO**
Have you read and received a copy of the attached information sheet?	**YES**	**NO**
Do you understand there are no benefits or risks involved in taking part in this study?	**YES**	**NO**
Do you understand that you are free to withdraw from this study at any time without having to give a reason and without affecting your future medical care?	**YES**	**NO**
Has the issue of confidentiality been described to you, and do you understand who will have access to the information you provide?	**YES**	**NO**
Have you had an opportunity to ask question and discuss this study?	**YES**	**NO**

Who explained this study to you? ______________________________

I agree to take part in this study. **YES** **NO**

Signature of participant ______________________________ Date ____________

(Printed Name) ______________________________

Signature of Witness ______________________________

Signature of Investigator or Designee ______________________________

UNIVERSITY OF ALBERTA HIP AND KNEE REPLACEMENT IN THE CAPITAL HEALTH REGION

Name				Sex	☐ Male ☐ Female	Age	
Site	☐ Hip ☐ Knee	Side	☐ Right ☐ Left ☐ Both			Personal Health #	
Height		Weight		Referral Date		Waiting List Date	
Home Phone				Work Phone			
Address						SURVEY DATE	

WOMAC SCALE

You are being asked to indicate on this scale the amount of pain, stiffness, or disability you are experiencing. The further you place your 'X' to the right, the more pain, stiffness or disability you are indicating that you experience.

The following questions concern the amount of pain you are currently experiencing due to arthritis in your hips and/or knees. For each situation please tell me the amount of pain recently experienced.

Question: How much pain do you have?

1. Walking on a flat surface.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
2. Going up or down stairs.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
3. At night while in bed.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
4. Sitting or lying.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
5. Standing upright.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme

The following questions concern the amount of joint stiffness (not pain) you are currently experiencing due to arthritis in your hips and/or knees. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

6. How severe is your stiffness after first wakening in the morning?	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
7. How severe is your stiffness after sitting, lying, or resting later in the day?	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you are currently experiencing due to arthritis in your hips and/or knees.

Question: What degree of difficulty do have with-?

8. Descending stairs.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
9. Ascending stairs.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
10. Rising from sitting.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
11. Standing.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
12. Bending to floor.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
13. Walking on flat.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
14. Getting in/out of car.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
15. Going shopping.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
16. Putting on socks/stockings.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
17. Rising from bed.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
18. Taking off socks/stockings.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
19. Lying in bed.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
20. Getting in/out of bath.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
21. Sitting.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
22. Getting on/off toilet.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
23. Heavy domestic duties.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme
24. Light domestic duties.	◯ 1. None	◯ 2. Mild	◯ 3.Moderate	◯ 4. Severe	◯ 5.Extreme

SF-36 HEALTH SURVEY

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent 1

Very good 2

Good 3

Fair 4

Poor 5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

Much better now than one year ago 1

Somewhat better now than one year ago 2

About the same as one year ago 3

Somewhat worse now than one year ago 4

Much worse now than one year ago 5

1

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a kilometre	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

4

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

By placing a tick (thus ☑) in one box in each group below, please indicate which statements best describe your own health state today.

Mobility
I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

Self-Care
I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities *(e.g. work, study, housework, family or leisure activities)*
I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

Pain/Discomfort
I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

Anxiety/Depression
I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

Compared with my general level of health over the past 12 months, my health state today is:

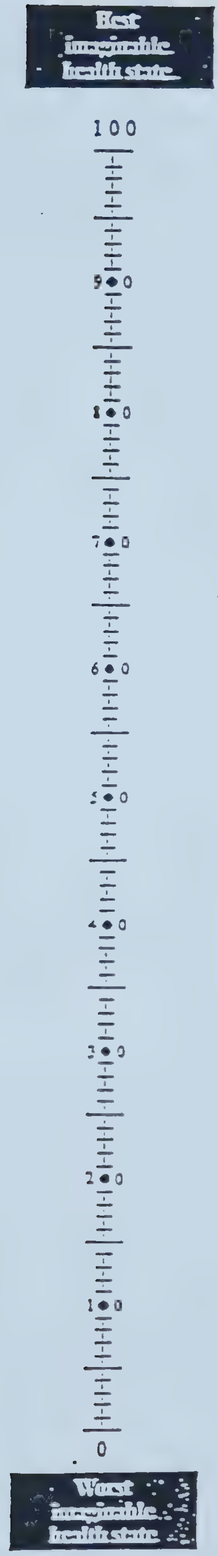
Better ☐ PLEASE TICK
Much the same ☐ ONE
Worse ☐ BOX

EUROQOL INSTRUMENT

2

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale how good or bad is your own health today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your current health state is.



Your own health state today

4. About how many times did you talk to someone-friends, relatives, or others on the telephone in the past week (either you called them or they called you)?			
◯ Not at all 1	◯ Once 2	◯ 2-6 times 3	◯ Once a day or more 4
5. How many times during the past week did you spend some time with someone who does not live with you; th is you went to see them or they came to visit you, or you went out to do things together?			
◯ Not at all 1	◯ Once 2	◯ 2-6 times 3	◯ Once a day or more 4

6. Do you see your relatives and friends as often as you want to, or not?	◯ 1. As often as wants to	◯ 2. Not as often as wants to
7. Is there someone who would give you any help at all if you were sick or disabled, for example your husband/wife, a member of your family, or a friend?	◯ 1. Yes	◯ 2. No one willing and able to help
8a. Is there someone who would take care of you now and then (taking you to the doctor or getting you groceries, etc.)?	◯ 1. Yes	◯ 2. No one willing and able to help

8b. Who is this person?

◯ 1. Spouse
◯ 2. Sibling
◯ 3. Offspring
◯ 4. Grandchild
◯ 5. Other kin
◯ 6. Friend
◯ 7. Other

9a. Is there someone who would take care of you for a short time (a few weeks to six months)?	◯ 1. Yes	◯ 2. No one willing and able to help

9b. Who is this person?

◯ 1. Spouse
◯ 2. Sibling
◯ 3. Offspring
◯ 4. Grandchild
◯ 5. Other kin
◯ 6. Friend
◯ 7. Other

10a. Is there someone who would take care of you for as long as needed?	◯ 1. Yes	◯ 2. No one willing and able to help

10b. Who is this person?

◯ 1. Spouse
◯ 2. Sibling
◯ 3. Offspring
◯ 4. Grandchild
◯ 5. Other kin
◯ 6. Friend
◯ 7. Other

OTHER INFORMATION

1. Do you presently suffer from or are you being treated for any of the following chronic conditions?

- ◯ 1. Serious trouble with back pain.
- ◯ 2. Other serious problems with joints or bones.
- ◯ 3. Circulatory problems.
- ◯ 4. Heart disease.
- ◯ 5. Emphysema or chronic bronchitis or persistent cough.
- ◯ 6. Arthritis or rheumatism.
- ◯ 7. Moderate or severe kidney disease.(eg. transplant or dialysis patient)
- ◯ 8. Asthma
- ◯ 9. Digestive problems
- ◯ 10. Cancer
- ◯ 11. Eye problems, for example, glaucoma, cataracts.
- ◯ 12. Diabetes
- ◯ 13. Severe Diabetes (Some organ or eye damage)
- ◯ 14. Stomach ulcer.
- ◯ 15. High blood pressure or hypertension.
- ◯ 16. Skin allergies or other skin disease.
- ◯ 17. Goitre or thyroid trouble.
- ◯ 18. Hay fever or other allergies.
- ◯ 19. Epilepsy.
- ◯ 20. Paralysis or speech problems due to stroke.
- ◯ 21. Liver disease (eg. chronic hepatitis)
- ◯ 22. Moderate or severe liver disease (eg. severe cirrhosis)
- ◯ 23. Other chronic health problem

2. Who lives with you? (check all that apply)

- ◯ No one
- ◯ Husband or wife
- ◯ Children
- ◯ Grandchildren
- ◯ Parents
- ◯ Grandparents
- ◯ Brothers and/or sisters
- ◯ Other relatives
- ◯ Other relatives
- ◯ Friends
- ◯ Other
- ◯ Non-related paid helper

3. How many people do you know well enough to visit within their homes?

◯ None 1	◯ One or two 2	◯ Three or four 3	◯ Five or more 4

11. What medications are you presently taking to manage pain?

MEDICATION	DOSAGE	FREQUENCY	COST

INJECTIONS(Please List)

12. Have you had a previous joint replaced?	◯ 1. Yes ◯ 2. No	Date of Replacement	
13. If yes to #12, which?	◯ 1. Hip	◯ 2. Knee	
14. What is the highest level of education that you have attained?	◯ 1.Grade 8 or less. ◯ 2. Partial high school. ◯ 3. Completed high school. ◯ 4. Partial technical school or university. ◯ 5. Completed technical school. ◯ 6. Completed university.	15. Residence type.	◯ 1.Apartment. ◯ 2. Condominium. ◯ 3. House. ◯ 4. Senior's complex. ◯ 5. Nursing home.
16. What is your first language?	◯ 1. English	◯ 2. French	◯ 3. Other
17. If you could have surgery sooner by changing surgeons, would you?	◯ 1. Yes	◯ 2. No	
18. In the last 2 weeks, have you had any visits with:			

			If yes, how many?	Did you pay for this service yourself?		
Physiotherapists	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Occupational Therapists	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Social Workers	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Nutritionists	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Community Nurses	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Research Nurses	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Chiropractors	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Homemakers	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Meals on Wheels	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Psychologists	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes
Other	◯ No	◯ Yes	______	◯ No	◯ Part	◯ Yes

19. What type of aids do you use in getting around? (mark all that apply)
◯ None ◯ Cane ◯ One Crutch ◯ Two Canes ◯ Two Crutches ◯ Walker ◯ Knee Brace ◯ Ankle Brace
20. What is your current employment status? (mark all that apply)
◯ Working full time ◯ Working part time ◯ Self-employed ◯ Student ◯ Homemaker ◯ On sick leave ◯ On Workers' Compensation ◯ On Unemployment Insurance ◯ On Disability Plan ◯ Retired from work ◯ Receiving a pension ◯ Unemployed
21. Approximately what is your family's combined monthly income before deductions from all sources?
◯ 1. $0 to $499 ◯ 2. $500 to $999 ◯ 3. $1,000 to $1,999 ◯ 4. $2,000 to $2,999 ◯ 5. $3,000 to $3,999 ◯ 6. $4,000 to $4,999 ◯ 7. $5,000 to $5,999 ◯ 8. $6, 000 or over
22. All together, how many people live on this income?

APPENDIX B

VARIABLES: Source and Type of Classification

Table B-1: Measured variables.

Measures: independent variable		Source	Type of variable	Code
demographic	age	CIHI database /questionnaire chart review	continuous	years
	gender	questionnaire	categorical (2)	0: female; 1: male
	disease	chart review	categorical (2)	0: OA; 1: RA
	marital status	questionnaire	categorical (2)	0: single, widowed, separated; 1: married, common-law
socioeconomic	education	questionnaire	categorical (4)	1: grade 8 or less 2: partial high school 3: completed high school 4: completed technical/university
surgical	hospital	regional waitlist	categorical (2)	0: UAH; 1: RAH
	surgeon	regional waitlist	categorical (28)	each surgeon assigned a numerical code
	surgeon volume	regional waitlist	categorical (3)	1: low volume; 2: average; 3: high
	joint	regional waitlist	categorical (2)	0: hip; 1: knee
	side	regional waitlist	categorical (3)	0: both; 1: right; 2: left
	length of stay	chart review	continuous	number of days
	discharge location	chart review	categorical (8)	1: home alone; 2: home with spouse; 3: home with others; 4: nursing home; 5: transfer to subacute; 6: transfer to Glenrose; 7: transfer to acute hospital; 8: other
	prosthesis	chart review	categorial (5)	1: Wright; 2: Dupuis; 3: Osteonics/Stryker; 4: Richards; 5: Zimmer; 6: other
	Implant fixation	chart review	categorial (3)	0: cemented; 1: cementless; 2: hybrid
	complications	chart review / emergency admission- CIHI database	categorical (11)	0: none; 1: dislocation; 3: wound infection; 4: MI; 5: PE; 6: pneumonia; 7: sciatic/femoral/peroneal palsy; 8: acute confusion; 9: UTI; 10: CVA; 11· blood transfusion; 12: other

physical	height	chart review	continuous	metres
	Weight	chart review	continuous	kilogram
	ROM	clinical assessment	continuous	degrees
	walking distance	chart review	categorical (6)	0: unable; 1: indoors; 2: <1 block; 3: 1-5 blocks; 4: 6-10 blocks; 5:10+ blocks
	assistive devices	questionnaire; chart review	categorical (4)	0: none; 1: 1 cane or crutch; 2: 2 canes or crutches; 3: walker
	joint involvement	questionnaire; chart review	categorical (3)	0: unilateral; 1:previous replacement; 2:bilateral
	co-morbid conditions	questionnaire / CIHI database	continuous	total number of co-morbid conditions
	type of co-morbid conditions	questionnaire	categorical (12)	LBP/PVD/CVD/HBP/CPD/kidney disease/liver disease/visual/hearing/ CVA/diabetes/other
	medication	questionnaire	continuous	MQS score
	emergency visits	emergency data base	continuous	number of visits
	community rehabilitation	CHA community rehab database	categorical (4)	0: none; 1: private practice
Social Support	residence	questionnaire	categorical (7)	0: rural; 1: Edmonton; 2: St Albert; 3: Sherwood Park; 4: Stony Plain; 5: Spruce Grove; 6: Fort Saskatchewan
	accommodation	questionnaire	categorical (6)	1: house; 2: apartment; 3: condominium; 4: seniors complex; 5: nursing home; 6: other
	living arrangements	questionnaire	categorical (7)	0: no one; 1: spouse; 2: children/grandchildren; 3: parents; 4: other relatives; 5: friends; 6: paid helper; 7: other

Abbreviations

CIHI Canadian Institute for Health Information
CHA Capital Health Authority
MQS Medication Quantification Scale
RAH Royal Alexandra Hospital
UAH University of Alberta Hospital
CPD Chronic pulmonary disease
CVA Cerebral vascular accident
CVD Cardiovascular disease
HBP High blood pressure
MI Myocardial infarction
LBP Lower back pain
PVD Peripheral vascular disease
PE Pulmonary emboli
UTI Urinary tract infection

Appendix C

Statistical Analyses

The purposes of the analysis were :

1. to determine differences between the pre-operative and 6 months scores and quantify the magnitude of change within each joint group
2. to determine differences between the pre-operative and 6 months scores and identify differences between the 2 age groups for THA and TKA, and.
3. to determine whether there were clinical variables that identify patients who may not improve after surgery. Thus the objective was to develop a multiple linear regression model that would predict those outcomes of interest given clinically relevant variables.

Statistical analyses were performed using the SPSS software version 7.5. All statistical testing was performed with two-tailed tests and at a 0.05 level of significance.

Bivariate analyses

To achieve the objectives of this study, a series of exploratory analyses were performed. Data were stratified and separately analyzed in hip and knee groups. Subsequent analyses subdivided the cohort into two age groups; those patients 80 years or older as compared those 55 to 79 years of age.

To provide an initial description of the data, descriptive statistics such as frequency distributions, means and standard deviations were calculated for all variables. If the variables were not normally distributed, medians and quartiles were calculated. Chi square test and nonparametric ANOVA's were used to identify differences between categorical variables, and t-tests and ANOVA's performed to identify differences between continuous variables that were normally distributed. Nonparticipants were compared to participants using standard bivariate techniques to identify any systematic differences between the 2 groups. A similar comparison was completed to compare losses to follow-up to the final study population.

Definition of the Variables

The *outcomes of interest* as defined by the dependent variables will be the pain (5 items) and function (24 items) dimensions from the disease specific measure, WOMAC. Hence, 2 scores were used to describe pain and function.

To accurately describe the change between pre-operative and the 6 month follow-up scores, the scores were expressed using 2 methods. The first method of scoring used the difference of pre-operative scores and the 6 month follow-up evaluation. One would expect that patients with worse initial health to show a greater change in scoring than patients with good initial health because of the ceiling effect created

with the scoring. If the score was only expressed as a difference, those patients with minimal pain and disability would not have as great of change as those patients with extreme pain.

The other method used the *effect size*. This method standardizes group scores by calculating the difference between the pre-surgical and 6 month follow-up mean scores divided by the standard deviation of pre-operative scores. Because there is no accepted definition of clinical meaningful change for health status, standardization should be considered when comparing scores from different scalings such as the pain scores from the WOMAC and SF-36. It may also be used when comparing groups with different variances. For instance, the 80 years or older group will likely be smaller than the 55 to 79 years of age group and most likely will have a larger variance.

Chapter 3 objective: to describe the pain and functional outcomes of THA and TKA in a population based cohort.

The outcome of pain and functional scores from the WOMAC and SF-36 measures, as previously discussed. Change in pain and function from baseline to 6 months follow-up were tested for significant differences ($p \leq 0.05$). Paired t-tests compared the 2 group means: baseline and 6 month follow-up, based on the assumptions of normality and equal variances. It was anticipated these assumptions were upheld since a similar study examining the change in scores of THA over a similar time period reported normal distributions [MacWilliam et al, 1996]. Furthermore, the t-test is considered robust for moderate violations of these assumptions. The effect sizes were also examined for differences between joint groups.

Chapter 4 objective: determine whether patients 80 years or older attain similar pain and functional outcomes as patients 55 to 79 years of age

Differences between the pre-operative and 6 months scores were tested using paired t-tests within each age group. Given a normal distribution and relatively equal variances, two sample t-tests were subsequently performed to compare differences of the dependent measures between those participants 80 years and older and those younger. If homogeneity of variances was significantly different, then a pooled variance was not used for the t-ratio, but rather separate variances of the two groups. This occasionally occurred when the smaller groups, such as the group 80 years and older, have larger variances. A multiple linear regression was performed to control for confounding effects on age. A forced entry procedure was used with variables that were thought to affect age.

Chapter 5 objective: to identify those patient-related factors which determine pain and functional change seen after hip and knee arthroplasties.

Multiple Regression

Multiple linear regression analyses were used to analyze the relationship between one dependent variable and a set of independent variables. The general model for multiple regression is expressed as the following:

$$y = b_o + b_1x_1 + b_2x_2 + \ldots + b_K x_K + e$$

This linear regression equation predicts the value of the dependent variable, **y**, based on the predictor variables, **x**, and **b**, the unknown population coefficients for each independent variable. That is, for particular values of $x_1, x_2, \ldots, x_K$, an observed value of y is defined by the linear model. Where b_o is the coefficient of the constant and b_K is the coefficient of the kth independent variable. Regression coefficients are interpreted as weights that determine the amount each variable contributes to the explanation of the dependent variable. For instance, the dependent variable is expected to increase the amount of b_1 for every one unit increase of the independent variable, x_1, while keeping all other independent variables constant. Coefficients are determined by the ordinary least squares estimation. The random error, e, is assumed to be normally and independently distributed random variables.

Prior to the multivariate analyses, bivariate analyses with each independent variable was evaluated for its association with the outcome of interest. After those significant variables were identified, these variables were entered along with clinical meaningful variables to develop a regression model.

The regression model was constructed using two approaches. The first method used the *stepwise selection* of the independent variables. This process of variable selection first selects the variable with the largest correlation with the dependent variable. If the variable fails to meet the entry criterion according to the partial F-test, the procedure stops. When the first variable is entered, it is re-examined to determine whether it should be removed according to the removal criterion. The final entry and removal criterions were set at stringent levels of 0.05 and 0.10, respectively. Variables not in the equation were then considered individually for entry. After each step, all variables in the equation were considered for removal. The advantage of this method allows inspection of significant variables and permit maximum prediction accuracy with the smallest number of predictors; however, stepwise regression will not control for those non-significant variables.

The other approach was *forced entry*. All independent variables considered to be practically relevant were entered in the model regardless of the significance. The advantage of this approach is that non-significant variables and the respective coefficients are accounted for and included in the model.

To determine the 'goodness of fit' for a model, the coefficient of determination, R^2, was used. This value is the proportion of variance in the dependent variable, y, which is explained by the independent

variable. Possible values range from 0 to 1, where a value nearer to 1 indicates the independent variables in the model better explain the dependent variable. Although no set levels of acceptance are defined within the orthopaedic literature, a R^2 value of greater than 0.20 was considered as acceptable.

A potential problem in determining significant variables was *multicollinearity*. Variables that were highly associated with the dependent measure in a bivariate model, may become redundant in a multivariate model because of their correlation with other variables. Multicollinearity, the presence of highly correlated independent variables may yield the regression coefficients unstable. For example, age and gender scores may be correlated in the model. Large correlations were identified by the correlation matrix, assessing the goodness of fit of the model, R^2 , and inspecting the correlated variables individually to determine the more feasible one to enter into the model. Mutlicollinearity was not a problem with the variables analyzed in these analyses.

The assumptions of the least squares estimation of multiple regression are one of *linearity* and the other of *estimates of variance*; that is, normally distributed residuals and equal variances. These parameters were inspected for each subgroup (joint and age). When these assumptions are violated, transformation of data may be required; however, no transformations were required with this particular analyses. Change of pain and function scores were normally distributed (Fig. D-2).

Logistic Regression

When data are skewed and the assumption of linearity breached, a nonparametric method must be considered. Logistic regression was considered if the dependent variable was best described in dichotomous or multinominal terms. For example, pain as described by the SF-36 may not be as sensitive as the WOMAC; responses of the SF-36 may be polarized at the 2 extreme responses (i.e. present or absent). A logistic regression in this scenario would be appropriate.

Like ordinary linear regression, the logistic regression equation provides a coefficient for each predictor variables. In addition to providing an estimate of the outcome, each coefficient can also be converted to an odds ratio of the outcome; that is, an estimate of having pain or functional limitations. The logistic regression model is expressed as the following:

$$\ln (y / [1-y]) = b_o + b_1x_1 + b_2x_2 + \ldots + b_K x_K + e$$

Where y is the probability of the dichotomous outcome, $\ln [y / 1-y]$ is the natural logarithm of the odds of the dependent variable based on the predictor variables, **x**, and **b**, the unknown population coefficients for each independent variable. b_o is the coefficient of the constant and b_K is the coefficient of the kth independent variable. The random error, e is assumed to be binomial and independently distributed random variables. Logistic regression coefficients are interpreted as change in the logit for a change of one

unit in the independent variable. Because of the difficulty in interpretation, probabilities or odds ratios are used to interpret the dependent variables:

$$p(\text{outcome occurring}) = \frac{e^{(b_0 + b_1x_1 + b_2x_2 + \ldots + b_Kx_K)}}{1 + e^{(b_0 + b_1x_1 + b_2x_2 + \ldots + b_Kx_K)}}$$

An odds ratio (OR) greater than 1 is interpreted as an increased risk of developing the outcome, that is, showing no improvement in pain or function; whereas an OR of 1 indicates no effect.

This regression model used the same two approaches, stepwise selection and forced entry, as described with the multiple regression. Variance explained by the model is indicative of the predictive accuracy. Whereas in multiple regression the explained variance was described by the R^2; there is no true R^2 for logistic regression, but rather an approximate.

$$R_L^2 = \frac{-2\log L_0 - (-2\log L_1)}{-2\log L_0}$$

where L_0 = likelihood function for the model containing only the estimated intercept

L_1 = likelihood function for the model containing the estimates for all of the parameters

APPENDIX D

Summary data of joint groups for WOMAC and SF-36 scores

WOMAC and SF-36 scores with respect to joint

WOMAC

		PAIN				paired t-test				
		pre-op		6 month			difference		ES	
	n	mean	sd	mean	sd	sign	mean	sd	mean	sd
Hips	228	42.9	15.9	84.6	18.0	< 0.001	32.8	21.2	2.63	1.29
Knees	275	43.4	17.6	76.1	19.1	< 0.001	34.1	20.9	1.86	1.21

		FUNCTION				paired t-test				
		pre-op		6 month			difference		ES	
	n	mean	sd	mean	sd	sign	mean	sd	mean	sd
Hips	227	38.5	15.1	73.0	20.1	< 0.001	37.6	21.6	2.48	1.43
Knees	275	42.8	17.4	70.5	18.2	< 0.001	27.9	20.2	1.60	1.15

		STIFFNESS				paired t-test				
		pre-op		6 month			difference		ES	
	n	mean	sd	mean	sd	sign	mean	sd	mean	sd
Hips	228	39.0	20.1	73.0	20.1	< 0.001	34.0	25.1	1.71	1.26
Knees	275	39.7	21.5	63.4	22.0	< 0.001	23.7	25.2	1.10	1.18

independent t-test

	pain	function	stiffness
pre-op	0.769	0.004	0.707
6 mon	< 0.001	0.001	< 0.001
difference	< 0.001	< 0.001	< 0.001
ES	< 0.001	< 0.001	< 0.001

* difference = 6 month score- pre-operative score

ES = effect size = (6 month - pre-operative score) / pre-op standard deviation

paired t-test = comparison of pre-operative and 6 months measures

independent t-test = comparison of joints (hips & knees)

SF-36

		pre-op		6 mon		paired t-test pre:post	difference		ES		norm value		pre-op	6 mon
HIPS	*n*	mean	sd	mean	sd	sign	mean	sd	mean	sd	mean	sd	sign *	
bodily pain	228	26.0	15.0	62.3	25.9	< 0.001	36.2	27.1	2.40	1.81	67.0	25.9	< 0.001	< 0.05
physical function	228	19.1	17.2	48.5	27.8	< 0.001	29.8	29.0	1.69	1.63	69.1	27.0	< 0.001	< 0.001
role physical	228	8.6	20.5	43.3	41.2	< 0.001	34.8	43.7	1.68	2.12	64.4	40.2	< 0.001	< 0.001
health	228	61.4	21.6	68.7	22.7	< 0.001	7.2	20.9	0.33	0.98	63.1	21.9	ns	< 0.001
social function	228	49.9	28.3	76.9	26.7	< 0.001	27.1	30.6	0.95	1.07	79.5	25.9	< 0.001	ns
mental health	228	66.2	20.8	75.8	19.4	< 0.001	9.6	17.3	0.45	0.83	75.4	18.8	< 0.001	ns
role emotional	228	48.2	44.7	71.5	39.3	< 0.001	23.7	52.2	0.53	1.17	77.0	36.9	< 0.001	< 0.05
vitality	228	39.6	19.4	57.3	22.5	< 0.001	17.7	21.9	0.90	1.14	57.9	22.7	< 0.001	ns
pcs	228	25.2	6.3	37.6	10.7	< 0.001	12.5	10.9	1.99	1.74	43.5	11.1	< 0.001	< 0.001
mcs	228	48.3	12.3	53.3	10.5	< 0.001	5.2	11.2	0.42	0.92	51.4	10.1	< 0.001	< 0.01
KNEES														
bodily pain	276	30.8	17.6	53.4	22.8	< 0.001	22.9	23.6	1.30	1.35	66.5	26.1	< 0.001	< 0.001
physical function	276	21.0	18.1	44.8	25.3	< 0.001	24.0	24.9	1.32	1.38	67.6	27.6	< 0.001	< 0.001
role physical	276	12.0	24.7	35.2	40.0	< 0.001	23.8	42.1	0.95	1.7	62.7	40.9	< 0.001	< 0.001
health	276	62.1	19.4	64.5	19.8	0.027	2.6	19.1	0.14	0.99	62.2	22.1	ns	ns
social function	276	54.0	27.2	72.1	27.7	< 0.001	18.1	27.9	0.66	1.03	79.2	26.2	< 0.001	< 0.001
mental health	276	68.9	19.5	75.0	19.0	< 0.001	6.3	16.9	0.32	0.86	75.6	18.9	< 0.001	ns
role emotional	274	55.2	44.3	67.3	40.4	< 0.001	12.2	54.8	0.27	1.24	76.5	37.4	< 0.001	< 0.001
vitality	276	42.0	20.9	52.9	22.7	< 0.001	11.1	21.2	0.53	1.01	57.6	22.8	< 0.001	< 0.01
pcs	274	25.9	7.5	34.6	10.1	< 0.001	8.9	9.8	1.19	1.31	42.9	11.3	< 0.001	< 0.001
mcs	274	50.1	11.4	52.5	10.8	< 0.001	2.5	11.1	0.21	0.98	51.6	10.1	< 0.05	ns

independent t-test

	pre-op	6 mon	difference	ES
bodily pain	0.001	< 0.001	< 0.001	< 0.001
physical function	0.239	0.116	0.022	0.007
role physical	0.092	0.027	0.005	< 0.001
health	0.730	0.029	0.010	0.021
social function	0.100	0.050	0.001	0.003
mental health	0.143	0.622	0.030	0.072
role emotional	0.080	0.248	0.018	0.020
vitality	0.185	0.031	0.001	< 0.001
pcs	0.287	0.002	< 0.001	< 0.001
mcs	0.086	0.385	0.007	0.02

pcs= physical component score

mcs= mental component score

ns = p > 0.05

* comparison of pre-op and 6 mon values to norm

SF-36 pre-operative, 6 month and norm values: age and gender

HIPS		bodily		physical		role				social		mental		role				component summary scores			
F: 65+	n	pain	sd	function	sd	physical	sd	health	sd	function	sd	health	sd	emotional	sd	vitality	sd	pcs	sd	mcs	sd
pre-operative	95	24.3	15.1	15.9	16.3	6.6	16.0	65.5	20.1	48.9	30.3	67.6	21.6	49.5	44.9	38.4	19.4	24.3	5.9	49.1	12.3
6 month	95	63.2	25.8	43.4	28.4	41.8	40.0	68.6	20.5	76.1	29.7	76.4	21.9	75.1	38.6	55.9	23.4	36.3	10.1	54.2	11.5
norm	413	63.4	27.1	61.9	29.0	56.1	42.5	61.6	22.1	77.0	27.7	74.7	19.9	73.4	39.7	55.5	23.5	41.0	11.5	51.4	10.5
F: 55- 64																					
pre-operative	27	26.1	17.4	26.1	21.0	7.4	20.6	57.9	26.7	48.1	31.0	63.6	20.7	29.5	41.4	39.4	17.4	27.5	7.4	44.2	12.5
6 month	27	59.7	29.3	54.6	29.6	52.8	44.0	76.6	26.5	80.1	27.8	77.2	14.8	69.1	40.2	59.8	24.9	40.3	11.6	53.1	9.4
norm	164	66.6	25.3	73.1	26.7	71.6	39.8	62.9	23.4	79.4	27.0	73.4	19.7	79.5	34.6	58.1	23.4	45.0	11.6	50.6	10.2
F: 45- 54																					
pre-operative	10	22.3	13.1	13.5	11.1	2.5	7.9	50.8	25.3	48.8	17.1	65.5	19.6	40.0	41.0	34.0	19.1	22.1	3.1	47.2	11.7
6 month	10	65.2	28.8	49.5	29.6	47.5	50.6	60.6	29.5	75.0	25.7	77.2	18.4	63.3	48.3	59.5	27.4	38.0	13.7	52.3	11.7
norm	193	72.1	23.3	82.9	21.7	79.9	21.7	70.5	20.6	82.7	20.8	74.4	18.1	81.9	33.3	60.6	21.3	49.0	9.6	50.1	10.2
F: 35- 44																					
pre-operative	6	28.5	7.8	18.3	12.5	12.5	20.9	56.0	17.6	52.1	16.6	65.3	22.0	22.2	40.4	43.3	6.8	26.7	4.9	45.1	9.6
6 month	6	71.2	22.3	49.2	15.3	45.8	45.9	62.5	28.4	85.4	20.0	72.7	23.9	66.7	51.6	56.7	18.3	39.0	10.2	52.3	11.8
norm	239	79.4	21.2	91.4	14.7	89.8	24.8	77.6	15.9	88.5	18.1	77.0	16.4	85.5	28.1	65.5	18.7	51.4	8.3	48.8	9.5
M: 65+																					
pre-operative	54	27.0	12.2	18.9	16.9	4.6	15.4	56.5	20.2	47.9	26.9	65.9	21.5	52.8	46.9	36.9	22.2	24.1	5.8	48.4	13.0
6 month	54	60.9	26.0	49.6	26.4	37.0	38.8	65.6	22.6	74.5	25.8	73.0	19.1	65.4	38.8	55.9	22.4	37.3	10.1	51.5	10.6
norm	293	68.8	25.4	65.8	28.3	59.7	42.5	58.6	22.1	79.7	26.0	77.4	17.4	76.9	37.5	57.8	22.6	42.0	11.4	52.5	9.8
M: 55- 64																					
pre-operative	21	29.9	16.1	23.8	14.3	25.0	35.4	65.8	20.5	60.7	24.5	68.6	15.8	68.3	38.7	48.6	16.1	27.4	7.1	52.5	10.0
6 month	21	64.7	25.7	57.4	27.1	51.2	42.9	71.2	24.9	81.0	20.4	80.0	13.1	82.5	30.9	63.8	18.6	39.6	12.5	55.8	6.4
norm	105	68.5	26.1	79.9	25.5	76.0	36.7	66.6	23.3	83.6	22.0	76.9	18.7	81.1	34.0	63.0	21.4	46.9	10.8	51.6	9.1
M: 45- 54																					
pre-operative	12	28.0	19.4	22.1	20.3	16.7	30.8	59.3	20.7	47.9	31.0	57.3	21.9	36.1	41.3	45.0	16.9	28.4	6.1	43.9	12.9
6 month	12	55.4	24.9	48.8	28.9	39.6	47.0	68.4	18.8	74.0	21.0	72.0	20.3	58.3	47.4	53.3	16.6	37.5	11.8	50.2	9.8
norm	145	74.2	22.7	86.5	17.7	85.6	32.2	73.2	19.4	85.5	23.3	76.4	16.8	85.4	33.9	63.1	19.7	50.4	9.7	51.0	9.9
M: 35- 44																					
pre-operative	3	38.3	21.0	36.7	20.0	16.7	38.5	76.3	10.4	62.5	28.9	76.0	30.4	77.8	24.7	53.3	21.0	30.0	9.9	55.1	8.0
6 month	3	65.7	7.2	70.0	5.0	58.3	38.2	78.0	22.9	87.5	12.5	84.0	10.6	100.0	0.0	68.3	14.4	42.2	0.3	58.9	3.1
norm	239	79.4	21.2	91.4	14.7	89.8	24.8	77.6	15.9	88.5	18.1	77.0	16.4	85.5	28.1	65.5	18.7	53.0	7.0	51.0	8.9

KNEES		bodily		physical		role				social		mental		role				component summary scores			
F: 65+	n	pain	sd	function	sd	physical	sd	health	sd	function	sd	health	sd	emotional	sd	vitality	sd	pcs	sd	mcs	sd
pre-operative	121	29.7	17.1	18.7	15.7	11.1	21.7	61.3	19.6	54.6	27.5	69.2	19.4	56.4	44.2	39.8	20.4	25.0	6.7	50.5	11.0
6 month	120	53.5	22.2	41.1	22.7	32.1	35.9	64.9	19.6	72.2	26.5	73.9	19.5	71.9	38.7	50.3	23.8	33.5	9.5	53.0	11.1
norm	413	63.4	27.1	61.9	29.0	56.1	42.5	61.6	22.1	77.0	27.7	74.7	19.9	73.4	39.7	55.5	23.5	41.0	11.5	51.4	10.5
F: 55- 64																					
pre-operative	30	23.2	17.0	19.3	17.2	10.0	24.2	56.0	19.3	46.7	29.0	62.3	21.5	52.2	43.5	34.7	19.8	24.5	8.6	46.8	12.8
6 month	30	41.5	19.8	40.8	25.1	26.7	37.3	60.8	22.8	70.0	31.8	72.8	17.8	53.3	43.4	53.7	18.8	32.1	10.1	51.2	10.9
norm	164	66.6	25.3	73.1	26.7	71.6	39.8	62.9	23.4	79.4	27.0	73.4	19.7	79.5	34.6	58.1	23.4	45.0	11.6	50.6	10.2
F: 45- 54																					
pre-operative	8	29.0	19.2	22.0	13.7	6.3	11.6	60.3	17.0	53.1	31.9	54.0	17.1	41.7	49.6	35.6	24.6	27.5	5.6	43.7	11.9
6 month	8	43.3	22.1	35.7	24.8	28.1	38.8	61.5	20.0	64.1	28.7	67.5	17.2	37.5	41.5	50.0	23.3	33.1	6.9	46.9	11.5
norm	193	72.1	23.3	82.9	21.7	79.9	21.7	70.5	20.6	82.7	20.8	74.4	18.1	81.9	33.3	60.6	21.3	49.0	9.6	50.1	10.2
F: 35- 44																					
pre-operative	3	24.3	25.6	16.7	12.6	0.0	0.0	62.3	2.5	29.2	7.2	62.7	15.1	33.3	57.7	30.0	8.7	24.9	7.3	42.3	6.9
6 month	3	38.0	14.7	30.0	5.0	0.0	0.0	53.0	8.5	50.0	25.0	45.3	18.0	0.0	0.0	33.3	14.4	32.1	2.2	34.3	9.1
norm	239	79.4	21.2	91.4	14.7	89.8	24.8	77.6	15.9	88.5	18.1	77.0	16.4	85.5	28.1	65.5	18.7	51.4	8.3	48.8	9.5
M: 65+																					
pre-operative	78	36.6	18.2	23.4	21.1	13.5	26.9	63.9	19.2	57.4	26.2	72.5	19.0	59.0	45.2	46.9	20.9	26.8	8.2	52.0	11.1
6 month	76	61.9	23.3	54.1	27.2	46.3	43.2	66.4	18.8	74.7	27.9	79.6	18.0	70.7	39.1	57.0	24.4	38.2	10.8	53.1	10.0
norm	293	68.8	25.4	65.8	28.3	59.7	42.5	58.6	22.1	79.7	26.0	77.4	17.4	76.9	37.5	57.8	22.6	42.0	11.4	52.5	9.8
M: 55- 64																					
pre-operative	28	29.9	15.8	24.8	20.9	16.1	32.1	66.2	20.7	54.0	26.8	68.1	18.3	44.4	43.4	47.1	20.8	28.2	7.9	48.4	11.7
6 month	28	53.8	22.1	48.5	27.8	41.1	45.2	67.0	19.2	75.9	27.6	75.3	18.4	73.5	38.7	54.8	16.6	36.0	10.4	53.8	9.6
norm	105	68.5	26.1	79.9	25.5	76.0	36.7	66.6	23.3	83.6	22.0	76.9	18.7	81.1	34.0	63.0	21.4	46.9	10.8	51.6	9.1
M: 45- 54																					
pre-operative	7	31.4	7.8	27.1	16.0	17.9	37.4	66.0	21.7	51.8	25.4	77.1	15.1	66.7	33.3	52.1	21.0	26.6	6.1	53.8	11.3
6 month	7	35.6	9.4	30.0	16.8	3.6	9.4	51.7	26.8	53.6	24.7	70.3	16.9	47.6	37.8	55.0	19.6	26.5	5.6	50.2	12.7
norm	145	74.2	22.7	86.5	17.7	85.6	32.2	73.2	19.4	85.5	23.3	76.4	16.8	85.4	33.9	63.1	19.7	50.4	9.7	51.0	9.9
M: 35- 44																					
pre-operative	1	0.0		5.0		0.0		62.0		25.0		52.0		100.0		25.0		16.8		49.3	
6 month	1	31.0		15.0		50.0		62.0		75.0		92.0		100.0		50.0		23.3		64.8	
norm	239	79.4	21.2	91.4	14.7	89.8	24.8	77.6	15.9	88.5	18.1	77.0	16.4	85.5	28.1	65.5	18.7	53.0	7.0	51.0	8.9

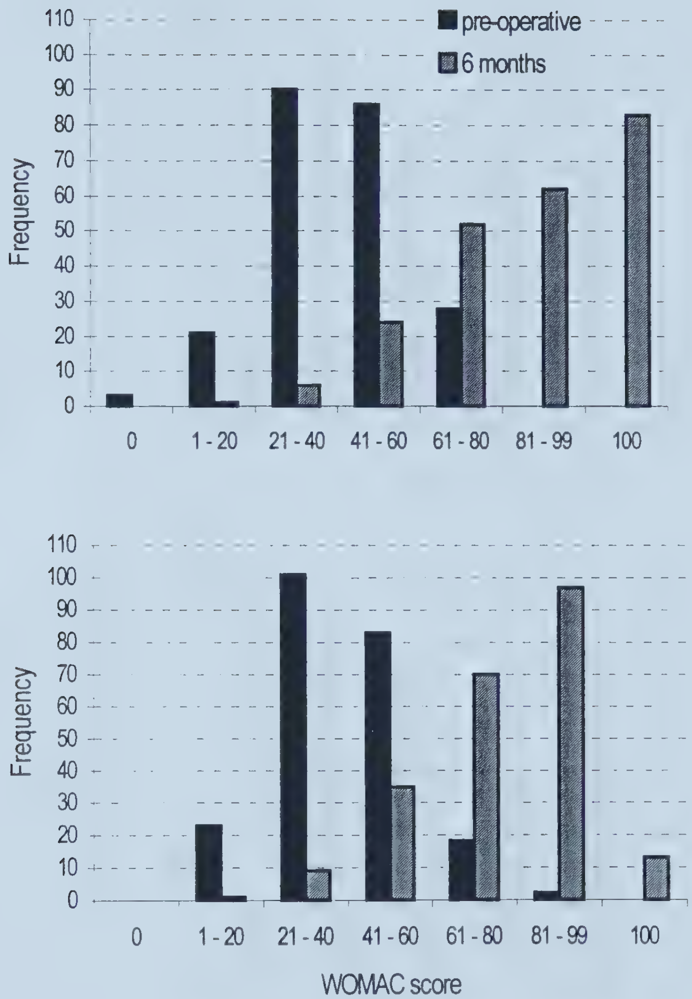


Figure D-1. Frequency distribution of pre-operative and 6 month WOMAC scores for patients with total hip arthroplasties (n = 228).

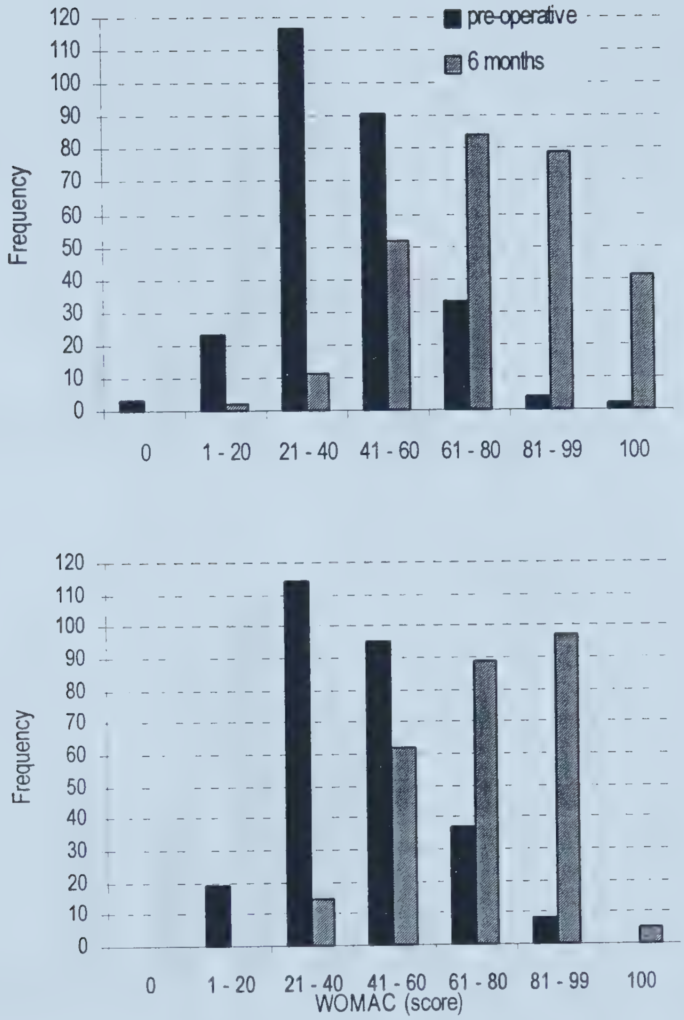


Figure D-2. Frequency distribution of pre-operative and 6 month WOMAC scores for patients with total knee arthroplasties (n = 273).

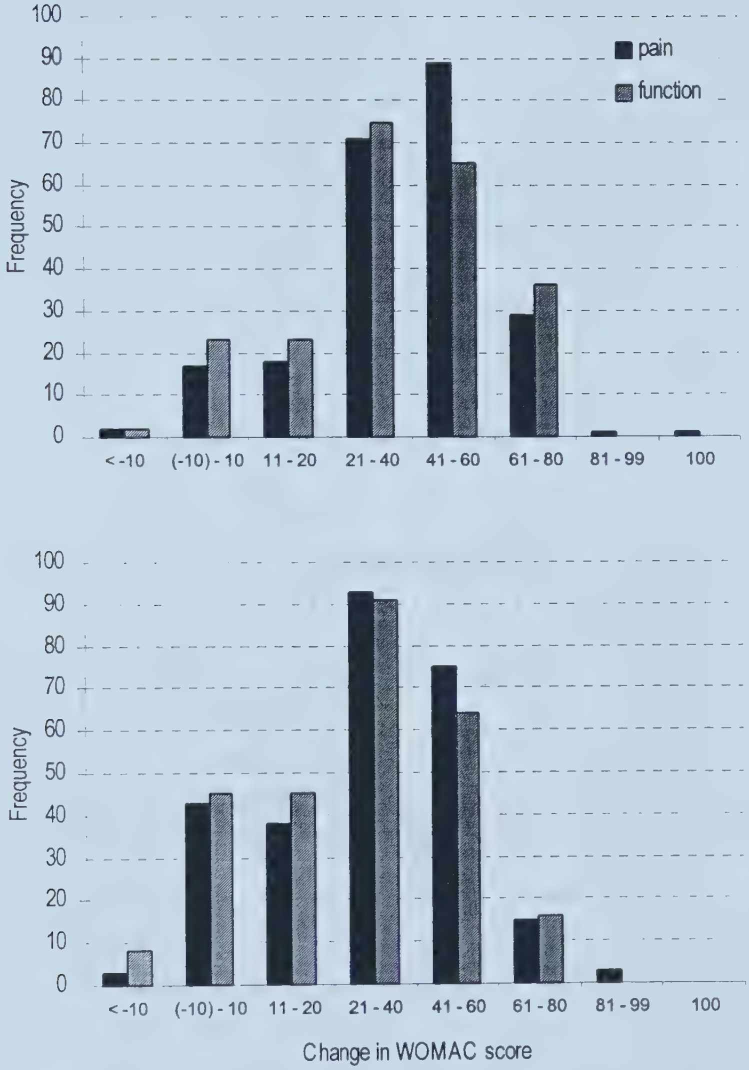


Figure D-3. Frequency distribution of change in pain and function for the total hip (*n*= 228) and knee arthroplasty (*n*= 273) groups. Normal distributions were seen for both joint groups.

Appendix E

Summary data of joint groups:

- baseline,
- peri-operative,
- ambulatory, and
- discharge variables

Summary of Baseline Variables

		THA			TKA		
Continuous variables							
VARIABLE	**source ***	***n***	**mean**	**sd**	***n***	**mean**	**sd**
Age (years)	cr	227	68.0	11.1	276	69.0	9.2
Body mass index (kg/m2)	cr	223	29.3	5.6	270	31.6	5.9
Comorbidities	pr	227	3.4	2.2	274	3.5	2.0
Waiting time for sx (days)	as	228	95.3	79.1	276	104.0	89.6
Assessment (days)	pr	227	23.1	40.5	274	16.9	29.5
Follow-up (months)	pr	227	6.4	0.6	271	6.3	0.5

Categorical variables					
VARIABLE	**source***	***n***	**percentage**	***n***	**percentage**
Gender	db	227		276	
male		90	39.5%	114	41.3%
female		138	60.5%	162	58.7%
Diagnosis	cr	226		274	
Osteoarthritis		214	94.7%	257	93.8%
Rheumatoid arthritis		12	5.3%	17	6.2%
Education	pr	228		269	
up to grade 8		41	18.0%	59	21.9%
some high school		47	20.6%	65	24.2%
high school completed		40	17.5%	54	20.1%
some technical/university		32	14.0%	29	10.8%
technical completed		35	15.4%	33	12.3%
university degree		33	14.5%	29	10.8%
Living alone pre-op	pr	228		276	
no		164	71.9%	209	75.7%
yes		64	28.1%	67	24.3%
Type of residence	pr	190		237	
house/condominium		177	93.2%	221	93.2%
senior complex		12	6.3%	16	6.8%
nursing home		1	0.5%	0	0.0%
Other joint involvement	cr	225		270	
contralateral		104		158	
ankles/feet		4		13	
wrists/hands		4		20	
back		15		14	
shoulders		10		19	
Previous TJA	cr	228		274	
unilateral		147	64.5%	194	70.8%
previous TJA within past 6 mon		3	1.3%	7	2.6%
previous TJA > 6 mon of this TJA		68	29.8%	60	21.9%
TJA to be done within 6 mon of this TJA		6	2.6%	12	4.4%
unknown TJA date		4	1.8%	1	0.4%

* cr = chart review
pr = patient report
db = database
as = assessment

Comorbid Conditions

Frequencies of self-reported comorbid conditions

condition	HIPS *n* = 228	KNEES *n* = 276	TOTAL *n* = 504
Musculo-skeletal			
back pain	87	71	158
joints	114	157	271
arthritis	186	234	420
Respiratory			
asthma	13	14	27
emphysema	19	15	34
Cardiovascular			
heart disease	29	35	64
circulatory	37	41	78
hypertension	72	107	179
Gastrointestinal			
stomach ulcer	19	30	49
digestive problem	32	35	67
Endocrine			
diabetes	14	25	39
severe diabetes	4	4	8
thyroid problem	31	25	56
liver disease	2	0	2
severe liver disease	1	1	2
Nervous system			
stroke	6	3	9
epilepsy	1	4	5
eye problem	38	51	89
Renal			
kidney disease	12	8	20
Allergies			
skin allergies	19	31	50
hay fever	18	23	41
cancer	12	25	37
other	10	16	26
no comorbidities	10	9	
	4.4%	3.3%	
mean	3.40	3.46	
standard deviation	2.22	1.97	
range	0-13	0-11	

Peri-operative Factors

VARIABLE	source **	THA n	THA percentage	TKA n	TKA percentage
Prosthesis fixation	cr	224		270	
cementless		82	36.6%	42	15.6%
hybrid		134	59.8%	157	58.1%
cemented		8	3.6%	71	26.3%
Complications	cr				
wound infection		4		5	
MI				1	
embolism				3	
pneumonia		4		1	
dislocation		1			
ICU admission		2		3	
thrombus		9		10	
UTI		14		18	
acute confusion		4		7	
other		39		47	
number of complications					
none		153	68.0%	180	66.7%
1		54	24.0%	73	27.0%
2		18	8.0%	17	6.3%
total		225		270	

		THA n	THA mean	THA sd	TKA n	TKA mean	TKA sd
length of stay (days)	cr	224	7.4	4.9	266	6.8	2.1

Ambulatory Status

VARIABLE	source **	THA n	THA percentage	TKA n	TKA percentage	
Walking devices pre-operative	cr	219		253		
none		85	38.8%	157	62.1%	
1 cane or crutch		101	46.1%	81	32.0%	
2 canes or crutches		14	6.4%	3	1.2%	
walker		19	8.7%	12	4.7%	
6 month	pr	239		274		
none		105	43.9%	148	54.0%	
1 cane or crutch		107	44.8%	112	40.9%	
2 canes or crutches		12	5.0%	9	3.3%	
walker		15	6.3%	5	1.8%	
distance walked pre-op	cr	214		252		
unable		0	0.0%	0	0.0%	
indoors		51	23.8%	19	7.5%	
< 1block		34	15.9%	67	26.6%	
1-5 blocks		95	44.4%	123	48.8%	
6-10 blocks		16	7.5%	22	8.7%	
10+		18	8.4%	21	8.3%	
regular exercise at 6 months	pr	224		271		
		166	74.1%	219	80.8%	
		n	**mean**	**sd**	*n*	**mean**	**sd**
ROM (degrees)							
pre-op flexion	as	195	78.1	21.7	259	106.4	15.5
6 month flexion	as	196	86.6	16.9	253	99.0	14.3

Discharge data

VARIABLE	source **	THA n	percentage	TKA n	percentage	
Discharge location	cr	225		272		
home alone		12	5.3%	16	5.9%	
home with others		119	52.9%	140	51.5%	
rehab centre		12	5.3%	14	5.1%	
subacute facility		76	33.8%	97	35.7%	
transfer to acute hospital		6	2.7%	5	1.8%	
transfer		94	41.8%	116	42.6%	
		mean	**sd**	**mean**	**sd**	**sign**
Acute care los	cr	7.39	4.86	6.78	1.88	0.064
Subacute los	cr	9.14	3.33	9.33	3.33	0.701
Readmission ER		***n***			***n***	
within 6 mon post-op	db	47			53	
1 mon prior		9			2	
		mean	**sd**	**mean**	**sd**	**sign**
days from discharge		62.6	52.8	55.7	48.9	0.496
Community Rehabilitation Program (CRP)						
received CRP (*n*)	db	55	24.1%	129	46.7%	< 0.001
- dc directly home		28	21.4%	64	41.0%	
- dc from rehab		27	28.7%	65	56.0%	
		mean	**sd**	**mean**	**sd**	**sign**
sx to contact time		43.5	41.3	37.9	55.7	0.504
- dc directly home		46.8	4.1	36.0	56.3	
- dc from rehab		41.5	36.8	40.3	55.9	
p value (indep t-test = dc home & transfer)		0.475		0.946		
contact to assessment		4.8	5.1	4.4	4.6	
treatment time		60.0	74.9	74.0	63.0	

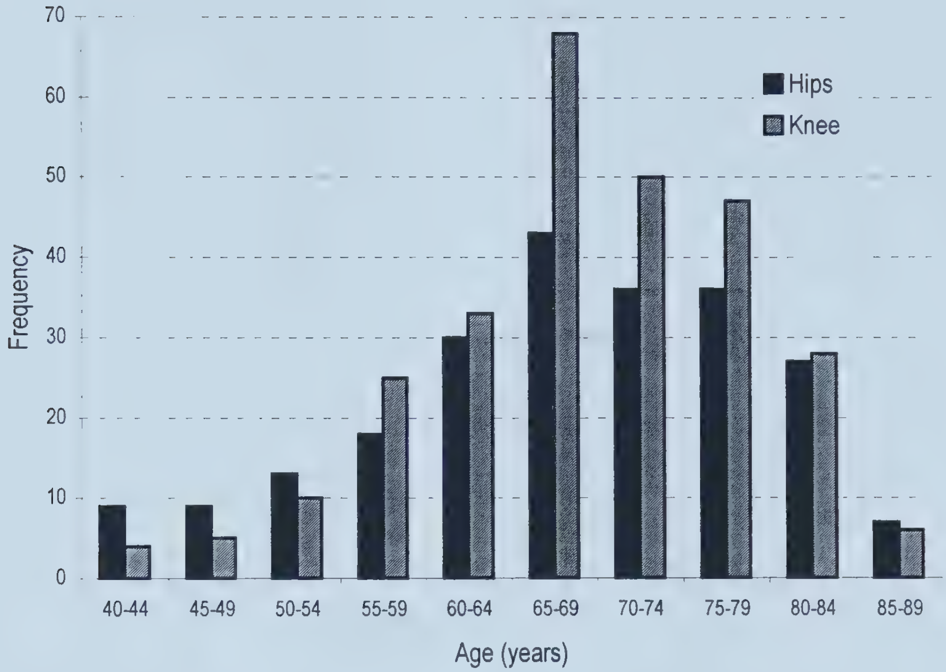


Figure E-1. Frequency of age for patients with total hip (n = 228) and knee (n = 276) arthroplasties.

APPENDIX F

Summary data of 55-79 year old and 80 or older age groups:

- WOMAC and SF-36 scores
- Comorbid conditions
- Discharge data

WOMAC and SF-36 scores with respect to age groups

WOMAC		PAIN				paired t-test				
	HIPS	pre-op		6 month			difference		ES	
	n	mean	sd	mean	sd	sign	mean	sd	mean	sd
55-79	163	42.9	16.0	84.0	17.0	< 0.001	41.2	19.7	2.58	1.23
80+	34	42.5	17.5	88.5	19.3	< 0.001	46.0	23.1	2.62	1.31
	KNEES									
55-79	221	43.6	17.9	77.6	18.8	< 0.001	34.1	20.9	1.91	1.18
80+	35	41.2	16.1	72.9	19.8	< 0.001	31.8	20.9	1.86	1.22

		FUNCTION				paired t-test				
	HIPS	pre-op		6 month			difference		ES	
	n	mean	sd	mean	sd	sign	mean	sd		
55-79	163	38.8	15.1	76.4	17.1	< 0.001	37.5	21.3	2.49	1.41
80+	34	35.7	15.2	76.7	23.4	< 0.001	41.0	23.3	2.73	1.55
	KNEES									
55-79	221	43.4	17.7	72.1	18.3	< 0.001	28.7	20.2	1.62	1.14
80+	35	38.2	12.0	66.2	16.7	< 0.001	28.1	17.6	1.89	1.18

		STIFFNESS				paired t-test				
	HIPS	pre-op		6 month			difference		ES	
	n	mean	sd	mean	sd	sign	mean	sd		
55-79	163	38.7	19.8	70.9	20.0	< 0.001	32.2	24.4	1.63	1.23
80+	34	40.8	22.5	80.9	19.8	< 0.001	40.1	29.3	1.78	1.30
	KNEES									
55-79	221	39.3	21.2	63.9	21.9	< 0.001	24.5	25.3	1.16	1.20
80+	35	43.4	21.1	65.1	23.2	< 0.001	21.7	25.0	1.04	1.11

independent t-test	HIPS			KNEES		
	pain	function	stiffness	pain	function	stiffness
pre-op	0.908	0.241	0.586	0.674	0.239	0.267
6 mon	0.171	0.799	0.009	0.169	0.089	0.779
difference	0.205	0.405	0.100	0.554	0.861	0.538
ES	0.855	0.392	0.516	0.802	0.223	0.570

* difference = 6 month score- pre-operative score

ES = effect size = (6 month - pre-operative score) / pre-op standard deviation

paired t-test = comparison of pre-operative and 6 months measures

independent t-test = comparison of age (< 80 & 80+)

SF-36						paired t-test								
	HIPS	pre-op		6 month			difference		ES		norm		pre-op	6 mon
55-79	*n*	mean	sd	mean	sd	sign	mean	sd	mean	sd	mean	sd	sign	sign
bodily pain	163	26.9	14.3	62.5	25.9	< 0.001	35.6	27.1	2.49	1.89	66.1	26.2	< 0.001	ns
physical function	163	20.2	17.8	50.0	26.7	< 0.001	29.8	29.0	1.68	1.63	67.1	28.0	< 0.001	< 0.001
role phsyical	163	9.2	21.1	44.9	41.2	< 0.001	35.7	44.3	1.69	2.09	62.2	41.3	< 0.001	< 0.001
health	163	61.8	21.5	69.7	22.1	< 0.001	7.9	20.9	0.37	0.97	61.7	22.4	ns	< 0.001
social function	163	51.2	27.9	79.0	25.2	< 0.001	27.8	30.0	1.00	1.07	79.0	26.4	< 0.001	ns
mental health	163	66.6	20.1	76.7	17.9	< 0.001	10.0	17.0	0.50	0.85	75.5	19.0	< 0.001	ns
role emotional	160	46.5	44.7	73.8	37.1	< 0.001	27.3	51.5	0.61	1.15	76.4	37.5	< 0.001	ns
vitality	163	40.4	18.7	58.3	22.0	< 0.001	17.9	21.8	0.96	1.16	57.5	23.0	< 0.001	ns
pcs	163	25.7	6.4	38.0	10.6	< 0.001	12.4	11.0	1.94	1.72	42.7	11.4	< 0.001	< 0.001
mcs	163	48.2	12.1	54.0	9.6	< 0.001	5.8	11.0	0.48	0.91	51.6	10.1	< 0.001	< 0.01
80+														
bodily pain	34	20.9	16.4	60.9	27.6	< 0.001	39.9	28.9	2.43	1.76	65.0	26.6	< 0.001	ns
physical function	34	12.8	13.3	38.9	33.0	< 0.001	26.1	27.3	1.96	2.05	63.0	28.8	< 0.001	< 0.001
role phsyical	34	2.9	13.4	33.8	36.9	< 0.001	30.9	37.5	2.30	2.79	57.2	42.5	< 0.001	< 0.01
health	34	63.1	21.5	66.4	24.7	0.325	3.3	19.0	0.15	0.89	60.8	22.1	ns	ns
social function	34	43.2	33.4	66.3	35.3	0.001	23.1	37.3	0.69	1.12	77.8	27.2	< 0.001	< 0.05
mental health	34	67.1	24.5	72.6	25.9	0.067	5.6	17.2	0.23	0.70	75.5	19.2	< 0.05	ns
role emotional	33	65.7	44.5	68.7	43.3	0.712	3.0	46.7	0.07	1.05	74.4	39.0	ns	ns
vitality	34	33.6	24.0	52.3	26.6	< 0.001	18.7	23.9	0.78	1.00	56.1	23.2	< 0.001	ns
pcs	34	21.9	4.9	35.0	10.5	< 0.001	13.0	11.3	2.63	2.29	41.3	11.5	< 0.001	< 0.01
mcs	33	50.4	13.6	51.3	14.3	0.406	1.7	11.4	0.12	0.84	51.8	10.3	ns	ns

	KNEES	pre-op		6 month			difference		ES		norm		pre-op	6 mon
55-79	*n*	mean	sd	mean	sd	sign	mean	sd	mean	sd	mean	sd	sign	sign
bodily pain	222	31.1	18.1	54.9	22.6	< 0.001	23.9	23.9	1.32	1.33	66.1	26.2	< 0.001	< 0.001
physical function	222	21.3	18.2	47.4	25.5	< 0.001	26.1	24.1	1.43	1.33	66.8	28.0	< 0.001	< 0.001
role physical	222	12.4	25.4	39.1	40.8	< 0.001	26.7	42.4	1.04	1.66	61.8	41.4	< 0.001	< 0.001
health	222	61.1	19.6	65.2	19.6	0.001	4.1	18.4	0.21	0.94	61.5	22.4	ns	< 0.05
social function	222	54.7	27.7	74.7	26.8	< 0.001	19.7	26.2	0.72	0.95	79.0	26.4	< 0.001	< 0.05
mental health	222	68.7	19.8	75.8	18.6	< 0.001	7.1	16.1	0.36	0.82	75.6	19.0	< 0.001	ns
role emotional	221	55.7	44.1	71.3	39.0	< 0.001	15.7	53.5	0.36	1.21	76.3	37.6	< 0.001	ns
vitality	222	42.3	21.3	53.9	22.5	< 0.001	11.6	20.4	0.55	0.96	57.5	22.9	< 0.001	< 0.05
pcs	222	25.9	7.7	35.5	10.3	< 0.001	9.6	9.7	1.26	1.26	42.6	11.4	< 0.001	< 0.001
mcs	222	50.2	11.5	53.2	10.5	< 0.001	3.1	10.7	0.27	0.93	51.7	10.1	< 0.05	< 0.05
80+														
bodily pain	35	29.3	12.5	52.6	24.9	< 0.001	23.3	23.2	1.51	1.50	65.1	26.6	< 0.001	< 0.01
physical function	35	16.6	17.0	35.2	23.3	0.001	18.6	30.3	0.96	1.56	63.1	28.7	< 0.001	< 0.001
role physical	35	6.6	15.5	21.3	33.8	0.031	14.7	38	0.77	1.99	57.2	42.5	< 0.001	< 0.001
health	35	67.1	19.7	64.5	20.3	0.432	-2.5	18.5	-0.13	0.94	60.7	22.1	ns	ns
social function	35	52.9	25.2	62.9	30.8	0.100	9.9	34.2	0.40	1.38	77.8	27.2	< 0.001	< 0.01
mental health	35	71.4	18.2	74.2	20.6	0.343	2.8	16.8	0.15	0.91	75.5	19.1	ns	ns
role emotional	34	53.5	46.3	57.6	42.7	0.701	4	60	0.09	1.29	74.5	39.0	< 0.01	< 0.01
vitality	35	39.3	18.6	48.3	24.6	0.044	9.1	25.4	0.48	1.34	56.2	23.2	< 0.001	ns
pcs	35	25.4	7.0	31.9	9.8	0.001	7.1	11.2	1.0	1.6	41.3	11.5	< 0.001	< 0.001
mcs	34	51.3	10.9	51.0	10.9	0.824	-0.4	11.4	-0.04	1.04	51.8	10.3	ns	ns

independent t-test	HIPS				KNEES			
	pre-op	6 mon	difference	ES	pre-op	6 mon	difference	ES
bodily pain	0.031	0.733	0.404	0.881	0.951	0.587	0.902	0.445
physical function	0.022	0.035	0.491	0.386	0.370	0.009	0.106	0.058
role physical	0.031	0.147	0.552	0.235	0.350	0.008	0.121	0.383
health	0.746	0.435	0.233	0.234	0.068	0.857	0.052	0.052
social function	0.150	0.043	0.429	0.142	0.706	0.020	0.048	0.087
mental health	0.914	0.393	0.168	0.082	0.349	0.635	0.147	0.169
role emotional	0.026	0.396	0.010	0.011	0.941	0.065	0.253	0.242
vitality	0.126	0.159	0.859	0.402	0.547	0.187	0.516	0.767
pcs	0.002	0.134	0.780	0.050	0.700	0.063	0.173	0.322
mcs	0.354	0.184	0.054	0.040	0.601	0.255	0.075	0.076

pcs= physical component score

mcs= mental component score

ns = not significant (> 0.05)

Comorbid Conditions

Frequencies of self-reported comorbid conditions

	HIPS		KNEES		TOTAL
	< 80	80+	< 80	80+	
condition	n = 163	n = 34	n = 222	n = 35	n = 454
Musculo-skeletal					
back pain	63	15	56	11	145
joints	85	17	123	24	249
arthritis	135	29	187	32	383
Respiratory					
asthma	9	2	11	1	23
emphysema	12	6	12	2	32
Cardiovascular					
heart disease	22	7	29	6	64
circulatory	27	9	31	10	77
hypertension	60	9	90	14	173
Gastrointestinal					
stomach ulcer	16	2	24	4	46
digestive problem	23	7	24	9	63
Endocrine					
diabetes	13	1	24	1	39
severe diabetes	4	0	3	1	8
thyroid problem	22	6	24	1	53
liver disease	1	0	0	0	1
severe liver disease	1	0	1	0	2
Nervous system					
stroke	5	1	3	0	9
epilepsy	0	1	3	0	4
eye problem	25	13	40	11	89
Renal					
kidney disease	9	2	5	2	18
Allergies					
skin allergies	17	2	28	3	50
hay fever	15	2	15	5	37
cancer	6	5	19	5	35
other	9	1	15	0	25
no comorbid conditions	8	0	8	0	
	4.9%	0%	3.6%	0%	
mean	3.55	4.03	3.46	4.06	
standard deviation	2.27	2.17	1.96	2.04	
range	0-13	1-8	0-11	1-8	
p-value	0.262		0.097		

Discharge data

VARIABLE	source **	THA					TKA				
		< 80		80+			< 80		80+		
Discharge location	cr	160		33			219		34		
home alone		10	6.3%	2	6.1%		12	5.5%	1	2.9%	
home with others		86	53.8%	8	24.2%		120	54.8%	5	14.7%	
rehab centre		7	4.4%	4	12.1%		10	4.6%	3	8.8%	
subacute facility		54	33.8%	17	51.5%		71	32.4%	25	73.5%	
transfer to acute hospital		3	1.9%	2	6.1%		6	2.7%	0	0.0%	
						sign					sign
transfer	cr	64	40.0%	23	69.7%	0.002	87	39.7%	28	82.4%	< 0.001
		mean	sd	mean	sd	sign	mean	sd	mean	sd	sign
Acute care los	cr	7.44	5.40	7.91	4.07	0.640	6.89	2.03	6.12	2.14	0.042
Subacute los	cr	9.19	3.38	8.59	2.92	0.512	9.03	2.73	10.46	4.5	0.153
Readmission ER											
within 6 mon post-op	db	30		10		0.337	40		10		0.301
1 mon prior		8		1			2		0		
		mean	sd	mean	sd	sign	mean	sd	mean	sd	sign
days from discharge		72.5	56.3	50.7	48.8	0.702	51.6	50.2	68.9	48.8	0.253
Community Rehabilititation Program (CRP)						sign					sign
received CRP (*n*)	db	41	25.2%	4	11.8%	0.091	104	46.8%	15	42.9%	0.660
received CRP after		21	32.8%	4	17.4%	0.161	49	57.0%	14	50.0%	0.519
subacute admission		mean	sd	mean	sd		mean	sd	mean	sd	
sx to contact time		46.8	46.8	41.5	13.5	0.824	35.8	49.0	60.4	98.3	0.356
contact to assessment		4.2	4.0	7.5	5.2	0.136	4.3	4.1	4.1	4.7	0.887
treatment time		52.7	40.0	83.8	80.0	0.302	67.1	52.9	62.9	59.7	0.794

APPENDIX G

Multiple regression residual plots

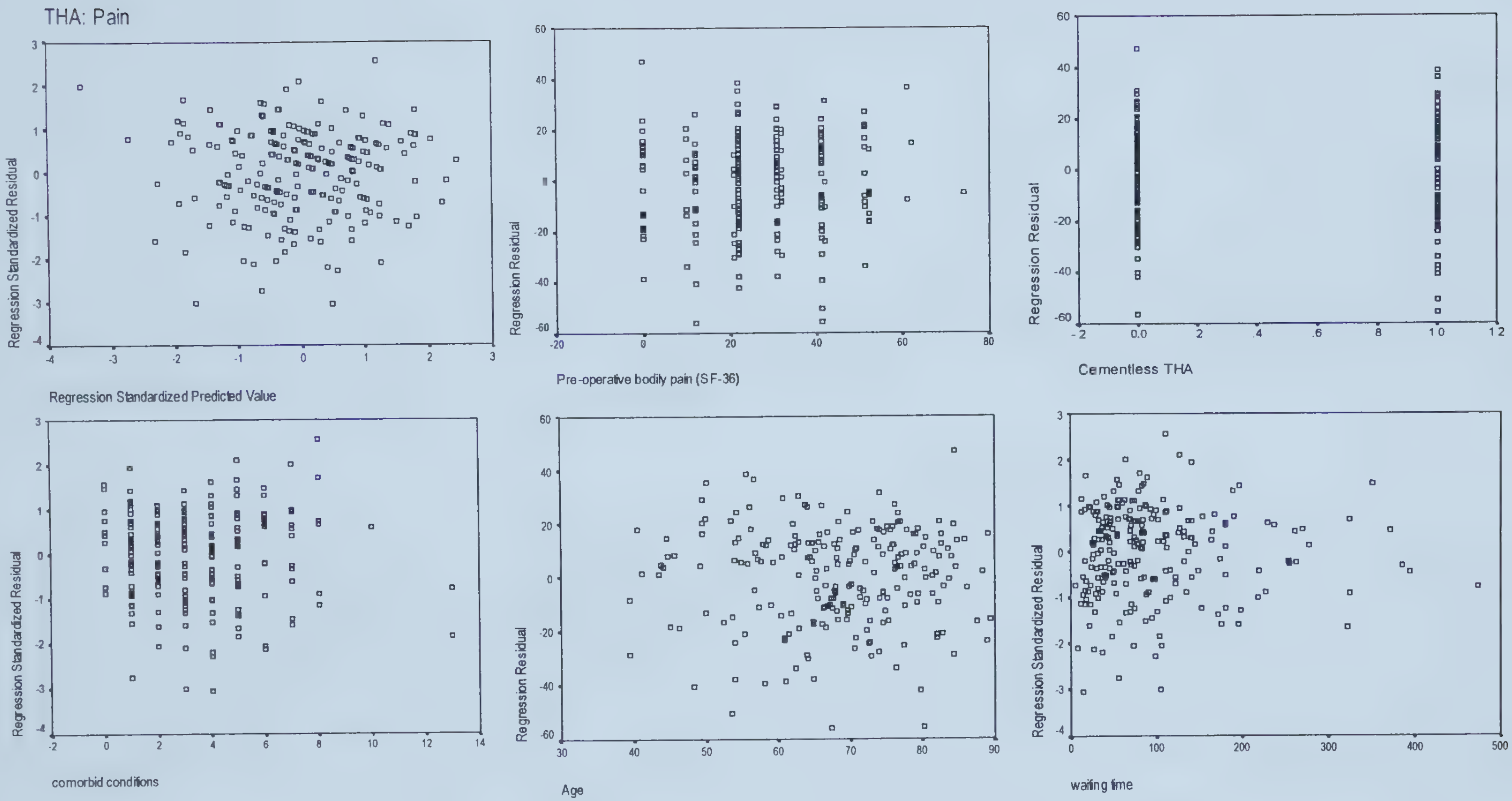


Figure G-1. Residual scatterplots for the regression model of pain (total hip arthroplasties)

TKA: Pain

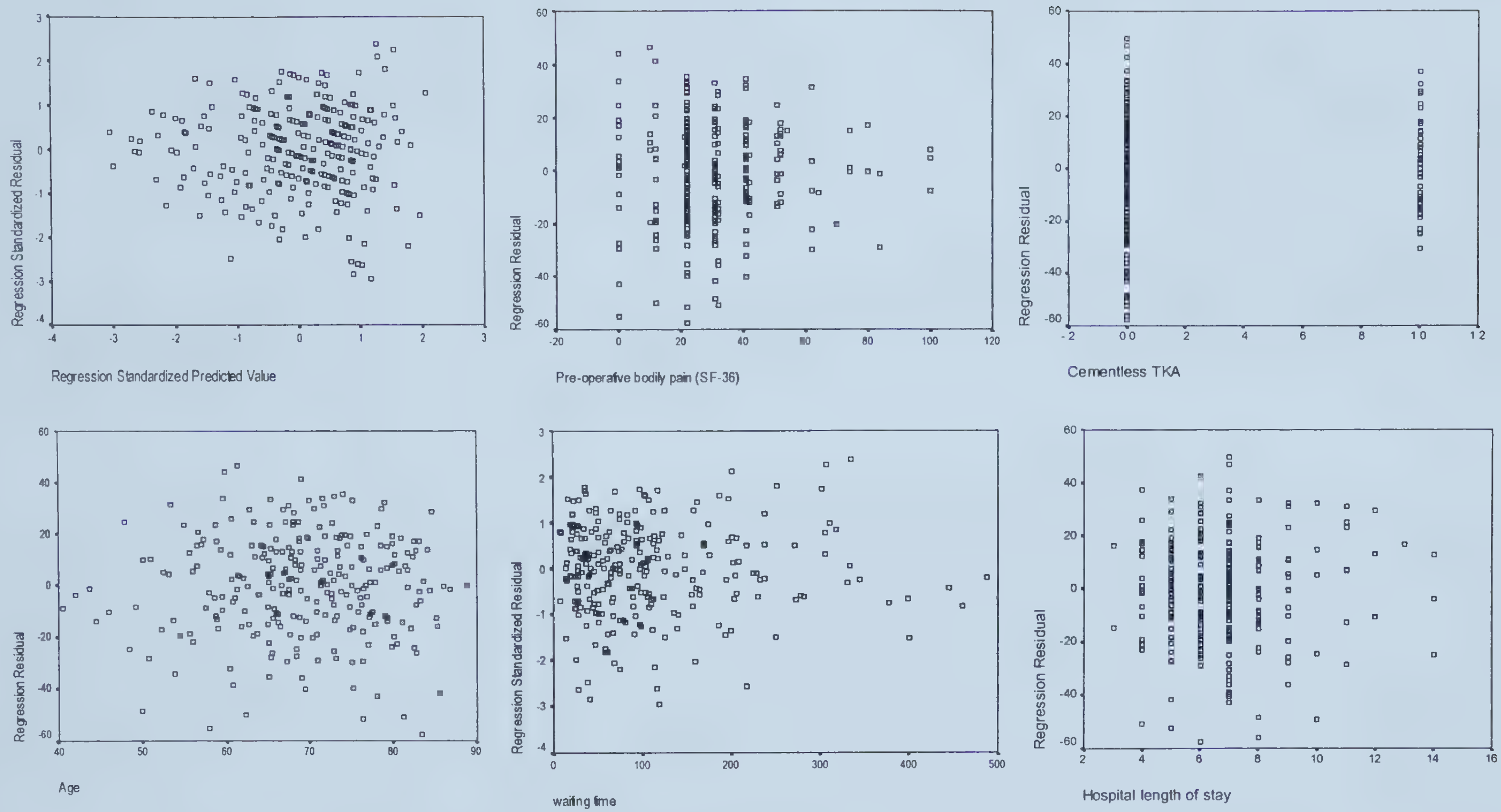


Figure G-2. Residual scatterplots for the regression model of pain (total knee arthroplasties)

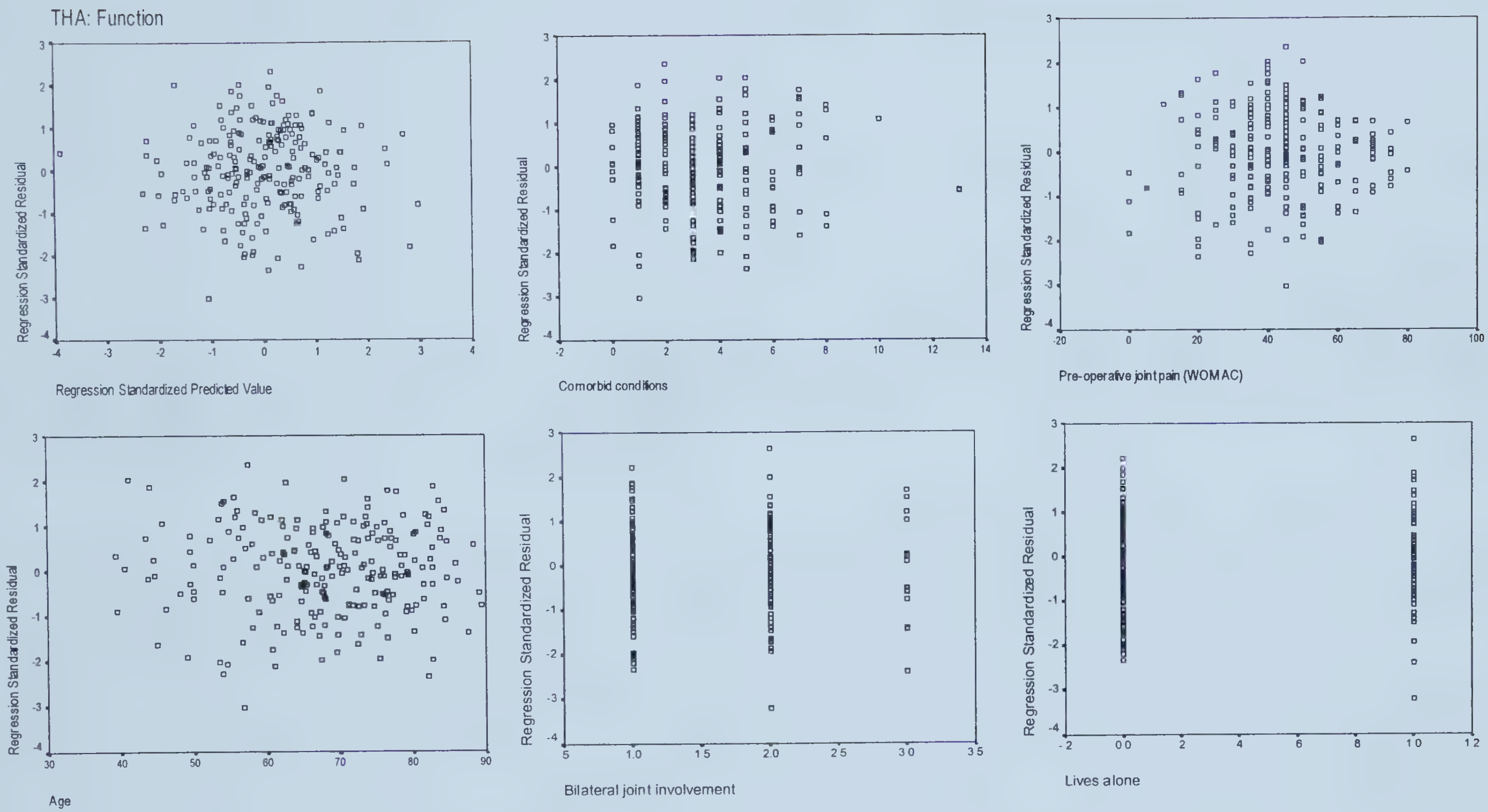
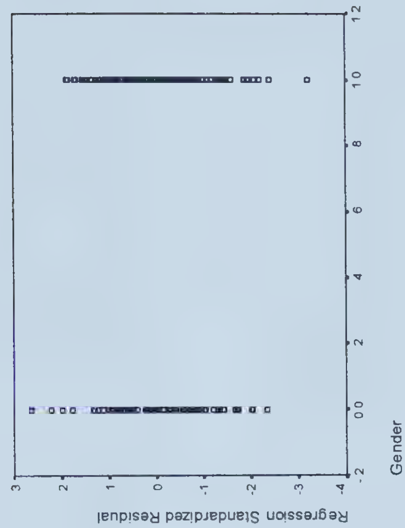
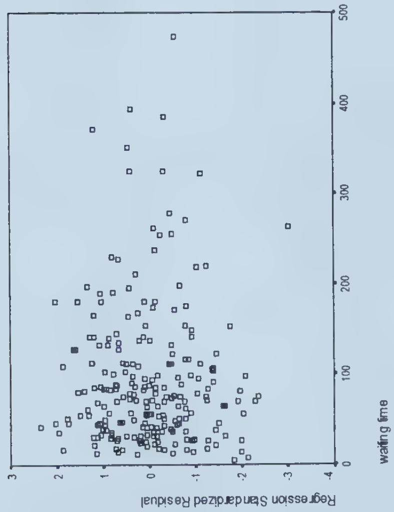
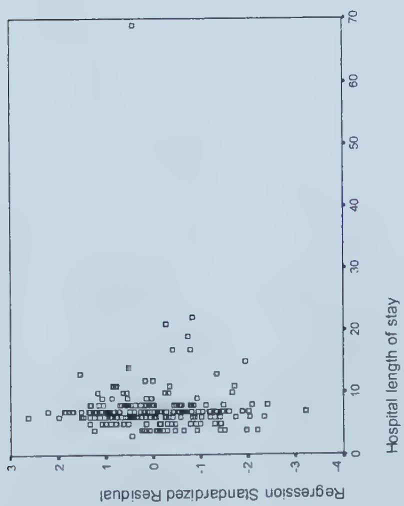


Figure G-3. Residual scatterplots for the regression model of function (total hip arthroplasties)


Regression Standardized Residual
Gender


Regression Standardized Residual
waiting time


Regression Standardized Residual
Hospital length of stay

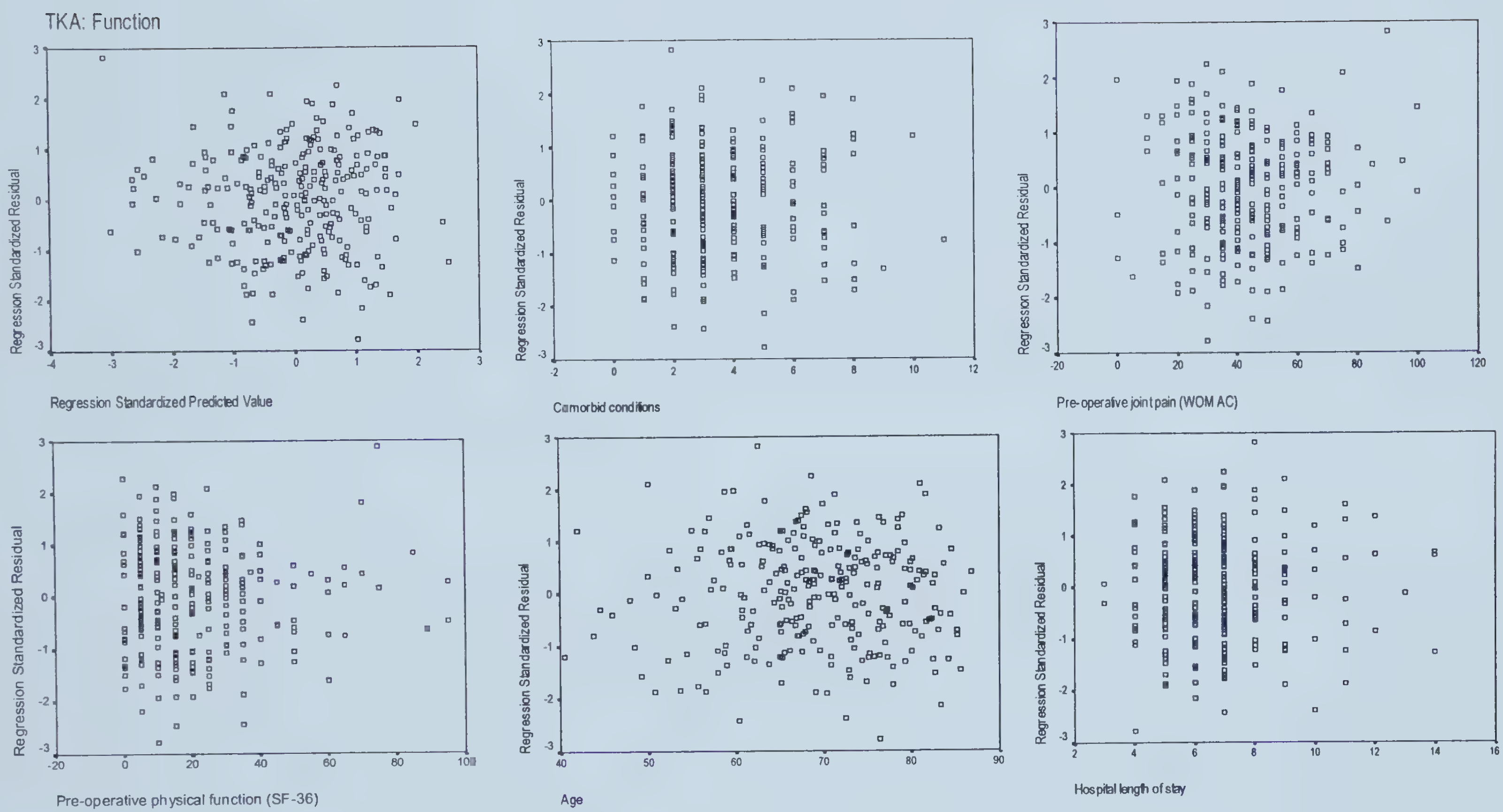


Figure G-4. Residual scatterplots for the regression model of function (total knee arthroplasties)